

2024

ENVIRONMENTAL IMPACT ASSESSMENT REPORT OF M/S CRYSTOLITE PHARMACEUTICALS

PLOT # 1 & 2, STREET S-2, NATIONAL INDUSTRIAL ZONE, RAWAT,
ISLAMABAD, PAKISTAN

Report Prepared By:

Pak Green Enviro-Engineering Pvt. Ltd

Address

46-M Block, Gulberg III, Lahore, Pakistan

Contact:

042-35441444, 0303-4442335

Email:

pak.green@hotmail.com; info@pakgreen.pk

URL:

www.pakgreen.pk



Report Submitted By:

M/s Crystolite Pharmaceuticals

Proponent:

Ali Raza

Address:

Plot # 1 & 2, street s-2, national industrial
zone, Rawat, Islamabad, Pakistan



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EXECUTIVE SUMMARY

TITLE & LOCATION OF THE PROJECT

Subject project for which this Environmental Impact Assessment (EIA) Study has been conducted is the proposed construction of pharmaceutical unit under the name of M/s Crystolite Pharmaceuticals located at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan, over an area of 21600 SFT. Covered area of plot is 12985 SFT and open area of plot is 8615 SFT.

PROJECT CAPACITY:

The Production capacity of the project will be approx., 6-8 lac Packs per month.

CATEGORY OF THE PROJECT:

The proposed pharmaceuticals units fall under category of Chemical Projects mentioned in Schedule-II, Category (B), Clause (2) of Punjab Environmental protection (Review of IEE/EIA) Regulations, 2022, hence such projects require submission of EIA Report to obtain Environmental Approval, under Section 12 of Punjab Environmental Protection Act 1997. TORs of the study under clause 5 (f) of policy and procedure for the filing, review and approval of environmental assessment are annexed as **Annexure-A** with this EIA report.

LOCATION

Subject unit is located at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan.

The Location Coordinates are:

33°31'12.60"N

73°14'19.95"E

Project land coordinates are as follows:

North = Access Road

South = Industrial Unit

East = Access Road

West = Access Road



Figure: Aerial View of The Proposed Project

NAME OF THE PROPONENT

Name: Mr. Ali Raza

CNIC# 33104-2121634-1

Mailing Address: Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan

For further details, CNIC of the proponent and other relevant documents (RCCI Industrial Estate Possession Letter and Plot allotment certificate) are attached with this report as **Annexure B.**

NAME OF ORGANIZATION PREPARING THE REPORT:

Pak Green Enviro-Engineering (Pvt.) Ltd, as independent consultants, has been appointed by

the proponent to conduct Environmental Impact Assessment Study.

Company office address: 46-M, Gulberg III, Lahore

Contact: 042-35441444, 0303-4442335.

For detail company profile see the Chapter # 1 “Introduction

STUDY TEAM

Sr. No.	Designation	Name/Qualification	Experience
1)	Chief Environmentalist/ Lead Environmental Professional	Abdul Hafeez Nasir PhD Scholar Environmental Management	Ten Years’ Experience as Environmental
2)	Senior Environmental/ Environmental Professional	Iftikhar Ahmed M.Phil Environmental Sciences	Eight Years’ Experience as Environmental
3)	Environmental professional	Sabeera Tauheed M.phil Environmental Science	3 Years’ Experience as Environmental
4)	Environmental professional/ Author of the report	Maham Ahsan MS. Environmental Science	1 Year Experience as Environmental

A BRIEF OUTLINE OF THE PROPOSAL

Name of the project:	Proposed Construction of pharmaceutical industry under the name of M/s Crystolite Pharmaceuticals
Location of the project:	Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan
Proposed Area:	Total area of the unit is around 21600 SFT. Covered area of plot is 12985 SFT and open area of plot is 8615 SFT.
Nature of Project:	Nature of the project is establishment of

	pharmaceutical industry for production of 1. Syrups 2. Sachets 3. Capsules 4. Soft Gelatin Capsule
Cost of the project:	Total cost of the project will be approx. 20 crores.
Project process:	The process cycle of production is based on Granulation, Compression/Encapsulation and Packing (Blister Packing) of medicines.
Production capacity	The Production capacity of the project will be approx., 6-8 lac Packs per month.
Power Requirement:	Power requirements of the project is being fulfilled by WAPDA with transformer of 360 K.W has been installed to full fill the energy requirement.
Labor/ Workforce:	During Operation: 20-25 persons (approximately).
Water Requirement:	During the operational phase of the project approx. 1728m ³ /day water will be required for project process and domestic purposes.
Solid waste:	During operation: 360-400 kg/day domestic and project related waste.

THE MAJOR IMPACTS

In order to identify all the activities associated with the project during operation phase with potential to cause adverse environmental impacts and harm a thorough review has been conducted. Project does not have any significant adverse impacts on the nearby community and on environment. Overall, the project has positive impacts on the local population and country as a whole. Moreover, area for plantation is also reserved for air purification within the project vicinity.

Table: Summary of Environmental impacts of the project during the project activities and their mitigation measures

Potential Impact	Criteria for determining Significance	Key Mitigation Measures
Solid waste Management — If solid waste will not be managed properly, it may cause negative impacts	Solid waste may produce in result of machinery installation e.g. wasted parts of machinery, wasted screws, nails and bolts. But most of the solid waste will be of domestic type.	Machinery installation waste should be sold in scrap as it can be used by steel and iron industry. Domestic waste should be disposed of properly, handed over to contractors, placed in bins; Proper solid waste management plan should be devised and implemented.
Waste water - water used for washing purposes	PEQS parameters	Waste water should be treated in the Effluent treatment plant and then disposed of in the nearest drain.
Noise - Noise may be generated during fitting and installation activities (drilling etc) and from generators at the project site; which may be a nuisance for the workers as well as neighbors	OSHA standards	Activities generating high levels of noise should be minimized at the project site. If the noise level will exceed the permissible limits with reference to Punjab Environmental Quality Standards and OSHA standards, following recommendations are suggested to take action against the high noise levels: • Ear muffs and ear plugs are recommended in case of high noise levels. • Rubber wounds should be

		placed underneath the generator to avoid the vibration.
Socioeconomic impacts—Inter-cultural differences between the project staff from other areas and the local community may arise due to the subject project. Positive socioeconomic impacts due to increased infrastructure, employment opportunities and economic growth.	No community complaints are expected. Increased employment facilities Increased infrastructure	Training of the non-local project staff on local culture and norms; Avoidance of unnecessary interaction of local population with the non-local project staff. Employment opportunities should be provided to the local people.

Table: Summary of Environmental impacts of the project during the construction phase of project and their mitigation measures

Potential Impact	Key Mitigation Measures
Dust Emissions- Particulate matter emissions during production activities can affect the air quality in the working area and be a nuisance for the workers' health. Gaseous emissions from site generators can result in deterioration of ambient air quality of the outdoor environment.	PPEs i.e. masks should be provided to workers during the working hours. Proper ventilation will be provided in the working area. Vehicles to use for the transportation of materials should be properly tuned. Monitoring should be conducted as per EPA PEQS Rules on regular intervals.
Machinery Noise- Working of machinery can be a nuisance for the workers in the working area.	PPEs i.e. ear muffs will be provided to workers in case of high noise.
Health & Safety Issues- Health and Safety issues e.g. Cuts and Injuries may be caused during the machinery handling.	Proper training of the staff should be conducted on regular basis to avoid the accidents and training record will be maintained by the management. First aid measures should be provided at the workplace. HSE policy will be formulated and implemented by management. Use of PPEs will be ensured during project activities.
Discharge of wastewater- The discharge of untreated wastewater can be a negative impact.	No wastewater will be disposed of into drain without having treatment in proposed septic tank. After treatment wastewater will be disposed of into nearest drainage system. Compliance of PEQS for Municipal and Liquid Industrial Effluents will be ensured.

	Monitoring will be conducted as per PEQS and reports will be submitted to EPA as per Rule (if required)
Solid waste management- Improper solid waste management may cause health problems and aesthetic issues	Waste bins will be placed at suitable areas at unit and contract will be made with EPA approved contractor for hazardous waste disposal. Domestic waste should be handed over to local contractors for safe disposal of the waste.
Groundwater —The increased withdrawal of groundwater for the project will affect the groundwater resources of the project area	No impact on the community groundwater needs is envisaged as a result of the project (ensured by management)

PROPOSED ENVIRONMENTAL MONITORING

To oversee the environmental performance of the project through its lifecycle enforcing the PEQS an Environmental Monitoring Program should be formulated which ensures effective surveillance of the environmental parameters at various stages of the project development and compliances with PEQS and legal obligations. Monitoring for following Environmental Parameters is recommended:

- **AMBIENT AIR**

Monitoring for ambient air should be conducted during operational activities of the project and report should be submitted to EPA Punjab.

- **NOISE**

Regular monitoring for noise level should be maintained periodically during operation phases of the project and report should be submitted to EPA Punjab as per rule.

- **WATER QUALITY**

Regular monitoring of water quality should be conducted during operational phases of the project and report should be submitted to EPA Punjab. Record should be maintained regarding the underground water pump and consumption.

Recommendation: Environmental Monitoring data log book should be maintained by the project proponent.

CHAPTER # 1

INTRODUCTION

This Section of the report provides an overview of the rational of the Project, objective of project, requirement of the project, purpose of the report and approach adopted to conduct the Environmental Impact Assessment Study.

PURPOSE OF THE REPORT

Environmental Impact Assessment (EIA) report is being submitted to the Environmental Protection Agency (EPA), Government of the Punjab, Lahore for the compliance of Section 12 of Punjab Environment Protection Act-1997 (Amended 2012) for obtaining No Objection Certificate (NOC). The other relevant regulations and guidelines considered while preparing this EIA report include:

- Policy and procedures for filing, review and approval of environmental assessments.
- Guidelines for the preparation and review of environmental reports.
- Guidelines for public participation.
- Guidelines for sensitive and critical areas.
- Detailed sectoral guidelines

Various aspects like environmental, social, physical and other aspects of the project both during construction and its regular occupancy are highlighted in this EIA report. Measures necessary to be adopted to mitigate any environmental impacts on any part of the environment around are also described. All the important information is also provided as described under the format used to help decision makers, EPA Punjab in the present case, before issuing the desired Environmental Approval.

IDENTIFICATION OF THE PROJECT AND PROPONENT

The proponent has been submitting this EIA report, the said project is proposed and the proponent wants to establish the pharmaceutical unit under the name of M/s Crystolite Pharmaceuticals and wants to get Environmental approval for said unit.

PROPONENT:

Name: Mr. Ali Raza

CNIC# 33104-2121634-1

Mailing Address: Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan.

For further details, CNIC of the proponent and other relevant documents (RCCI Industrial Estate Possession Letter and Plot allotment certificate) are attached as **Annexure-B**.

DETAILS OF CONSULTANT

Pak Green Enviro-Engineering (Pvt.) Ltd is an independent company, who conducts IEE, EIA, EMP and other environmental investigations through its panel of environmental consultants, public participation practitioners and experienced environmental managers. The company has its own recommended instruments to check the baseline environmental data/PEQS and lab analysis facility for water, waste water priority parameters.

Contact: Pak Green Enviro-Engineering (Pvt.) Ltd.

Office No. 46-M, Gullberg III, Lahore

Tel: 042-35441444, 03034442335

Email: info@pakgreen.pk; pak.green@hotmail.com

The current study was carried out by the following professionals:

Sr. No.	Designation	Name/Qualification	Experience
1)	Chief Environmentalist/ Lead Environmental Professional	Abdul Hafeez Nasir PhD Scholar Environmental Management	Ten Years' Experience as Environmentalist
2)	Senior Environmentalist/ Environmental Professional	Iftikhar Ahmed M.Phil Environmental Sciences	Eight Years' Experience as Environmentalist
3)	Environmental professional	Sabeera Tauheed M.phil Environmental Science	3 Years' Experience as Environmentalist
4)	Environmental professional/ Author of the report	Maham Ahsan MS. Environmental Science	1 Year Experience as Environmentalist

BRIEF DESCRIPTION OF NATURE, SIZE AND LOCATION OF PROJECT

Subject project is proposed project is the construction of the Pharmaceutical Unit under the name of Crytolite Pharmaceuticals located at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan. The Production capacity of the project will be approx., 6-8 lac Packs per month. The process cycle of production is based on Granulation, Compression/Encapsulation and Packing (Blister Packing) of medicines. The total cost of the project is 20 crore approx, and Total area of the project is 21600 SFT. Covered area of plot is 12985 SFT and open area of plot is 8615 SFT.

LOCATION

Subject unit is located at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan.

The Location Coordinates are:

33°31'12.60"N

73°14'19.95"E

Project land coordinates are as follows:

North = Access Road

South = Industrial Unit

East = Access Road

West = Access Road



Figure 1: Aerial view of the project site

SCOPING

SPATIAL AND TEMPORAL BOUNDARIES OF ENVIRONMENTAL ASSESSMENT

The project falls in Industrial area of district Rawalpindi. This project spans at the area of 21600 SFT. Covered area of plot is 12985 SFT and open area of plot is 8615 SFT. Various Industrial Units are already present around the vicinity of the project corridor. The main road along with the project site is Rawat Industrial Estate Road. The following map shows the spatial and temporal boundaries of the project. For further details, Google earth map of the project on A3 page is attached as **Annexure-C** and layout as **Annexure E** with the report.

IMPORTANT ISSUES AND CONCERNS RAISED DURING CONSULTATION

Important issue and concerns raised by the community during consultation include the impact of waste water released from the treatment plant that may impact the nearby community. The Proponent ensured that treated effluent from the treatment plant will be within limits of the PEQS and then disposed of into the nearest drain. Hence will not cause any issues to the community. The community was also concerned about employment for local people. The proponent made sure that maximum job opportunities for plant management and dyeing unit operation will be provided to the residents.

SIGNIFICANT IMPACTS TO BE DETERMINED

There can be impacts related to release of waste water containing chemicals into the nearby area. The proponent ensured the installation of treatment facility to treat the wastewater and then the safe disposal into nearby drain. Sludge produced if not disposed of properly can become a nuisance for nearby community especially due to its odor generation.

SCREENING

The project falls under category of Chemical Projects mentioned in Schedule-II, Category (B), Clause (2) of Punjab Environmental protection (Review of IEE/EIA) Regulations, 2022, hence such projects require submission of EIA Report to obtain Environmental Approval, under Section 12 of Punjab Environmental Protection Act 1997.

CHAPTER # 2

ANALYSIS OF ALTERNATIVES

This Chapter deals with the analytical overview of different alternatives that have been considered. The analysis has been carried out critically so as to justify the need of the Project and to select the most feasible alternative. Besides the economic viability; environmental sustainability and social soundness of the proposed Project has also been considered while analyzing different alternatives.

THE NO PROJECT ALTERNATIVE

Adopting zero-alternative would mean abandoning all the potential that the site offers to investor(s), contribution to government revenue and even local community livelihoods' improvement.

LOCATION/SITE ALTERNATIVES

To fulfill the commercial aspects of the project under reference of this EIA Report, it is to be sited at a place where commercial processing activity is either already going on or there are bright prospects of the same. Concurrently, it must also meet the legal requirements of the Punjab Environmental Protection Act, 1997 (Amended 2012). Availability of land at the best convenient place is equally important among other considerations for the site selection. Availability of access roads, communication facilities, electricity, basic infrastructure, sewerage etc. is yet the other necessary requirements.

Obviously, environmentally sound, neat and clean environment are the other considerations for site selection. The project will also facilitate the people of the area with increasing the opportunity of employment, and other related facilities.

Keeping these requirements and their feasibility and other basic infrastructural requirements, the selected site is ideally suited for Construction of the subject unit.

ALTERNATIVE SITE

No Alternative site has been considered due to insignificant environmental impacts. The proposed site fulfills the site selection criteria of Drug Regulatory of Pakistan, Ministry of health.

REASONS OF REJECTION

The reasons of rejection of this site are:

- High cost of land
- Nearby human settlements
- Due to the ownership conflict of surrounding land
- No proper communication facility
- Fauna & Floral Species are present at this site in abundance.

MODIFIED CONSTRUCTION TECHNOLOGY ALTERNATIVES

As the said project is proposed, there are no construction technology alternatives rather some alteration/renovation of the building will be done.

TECHNOLOGY ALTERNATIVES

The company intends to import brand new machinery from renowned international manufacturers of the world as well as from local market. Machinery is based on latest available technology to produce high quality medicines. The machines will also be having pollution remove technologies built in. Therefore, it the best option to use that technology.

CHAPTER # 3

DESCRIPTION OF THE PROJECT

TYPE AND CATEGORY OF THE PROJECT:

Subject project is proposed project is the construction of the Pharmaceutical Unit under the name of Crystolite Pharmaceuticals. located at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan. The Production capacity of the project will be approx., 6-8 lac Packs per month. The process cycle of production is based on Granulation, Compression/Encapsulation and Packing (Blister Packing) of medicines. The total cost of the project is 20 crore approx, and Total area of the project is 21600 SFT. Covered area of plot is 12985 SFT and open area of plot is 8615 SFT.

The project falls under category of Chemical Projects mentioned in Schedule-II, Category (B), Clause (2) of Punjab Environmental protection (Review of IEE/EIA) Regulations, 2022, hence such projects require submission of EIA Report to obtain Environmental Approval, under Section 12 of Punjab Environmental Protection Act 1997.

OBJECTIVES OF THE PROJECT

Objectives of the construction of the subject project are:

- To establish the business for the proponent.
- To contribute to the national economy of the country.
- Compensate to help poverty by providing employment.

LOCATION AND SITE LAYOUT OF THE PROJECT:

Subject unit is located at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan.

The Location Coordinates are:

33°31'12.60"N

73°14'19.95"E

Project land coordinates are as follows:

North = Access Road



South = Industrial Unit

East = Access Road

west = Access Road

For further details, layout map of the project is attached as **Annexure E**.



LAND USE ON SITE

Subject project is establishment of medicinal formulation unit. Area of the unit is industrial because unit is present at Rawat Industrial Estate.

ROAD ACCESS

Rawat Industrial Estate Road is present on to access the project, because subject project is present in Rawat Industrial Estate.

VEGETATION FEATURES OF THE PROJECT

The project does not have any significant vegetation features because surrounding of the area is clear.

COST AND MAGNITUDE OF THE OPERATION

Project is proposed pharmaceutical unit under the name of M/s Crystolite Pharmaceuticals. Total area of the project is 21600 SFT. Covered area of plot is 12985 SFT and open area of plot is 8615 SFT, the cost of the project is approx. 20 crores approx. There are no other associated activities with regard to the subject project.

SCHEDULE OF IMPLEMENTATION

Detailed feasibility studies and designing of the project have been completed. Necessary legal, administrative and financial formalities are being finalized. The project is expected to be completed within 16-17 months from the date of environmental approval. Subsequently the operational and maintenance aspects of the project will be undertaken by the proponent.

DESCRIPTION OF THE PROJECT:

The project aims to establish pharmaceutical unit under the name of Crystolite Pharmaceuticals. at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan. The project activities involve Syrups, Sachets, Capsules, Soft Gelatin Capsule, over an area of 21600 SFT. Covered area of plot is 12985 SFT and open area of plot is 8615 SFT.

DETAILED PROCESS

The proposed project is a construction of pharmaceutical unit which is going to be established at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan. The proposed site for the Crystolite Pharmaceuticals had been already under the possession of the owner. RCCI industrial estate possession letter and plot allotment certificate are attached as **Annexure-B**.

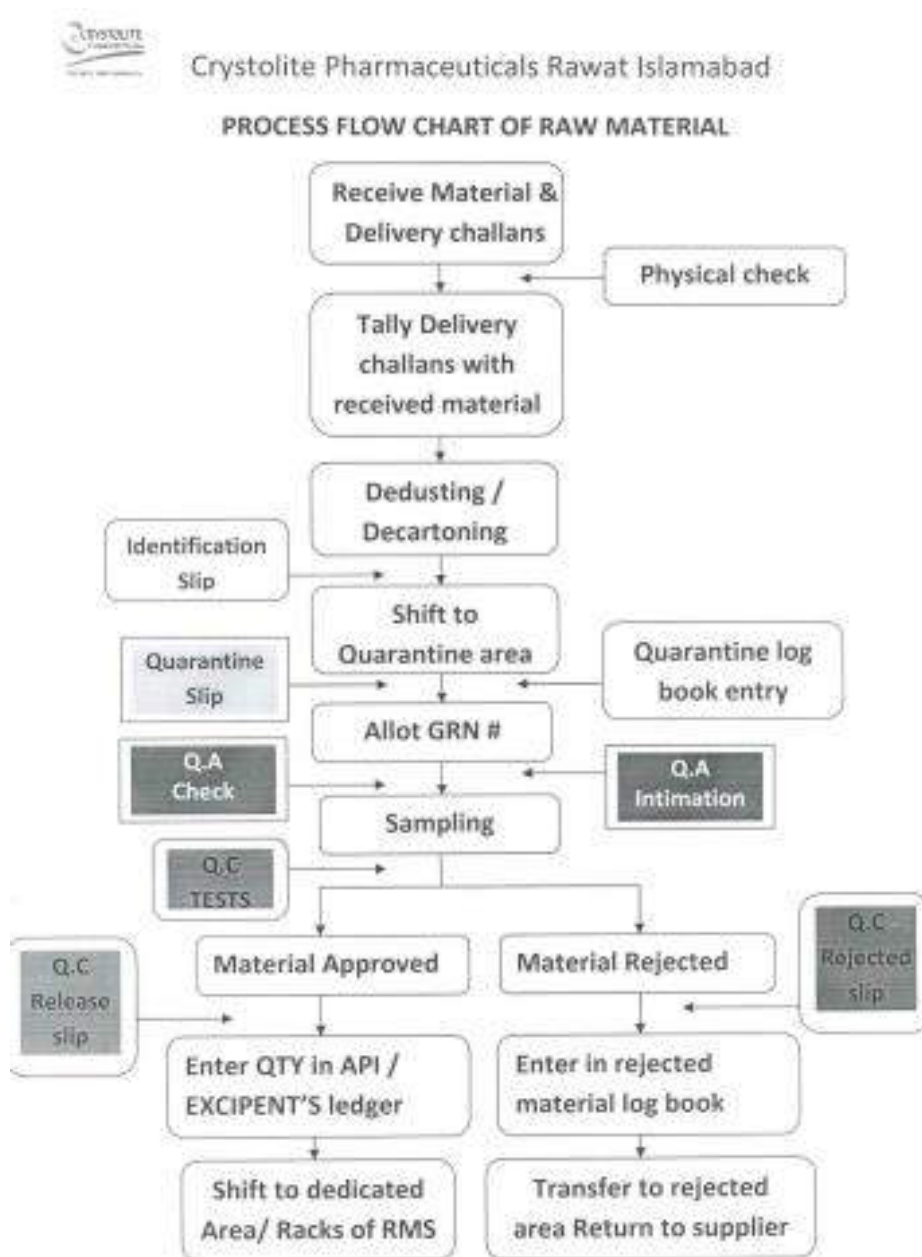
The proposed pharmaceutical unit will have production capacity approx., 6-8 lac Packs per month. The process cycle of production is based on Granulation, Compression/Encapsulation and Packing (Blister Packing) of medicines. The water will be used for production of syrup and line washing purpose. The process related wastewater will be treated through the wastewater treatment facility. About 20-man power will be required during construction phase and for operation phase 20 person will be required for operation of this proposed pharmaceutical unit. The proposed project will have modern air cleaning system (Heating Ventilation and Air Conditioning System) for control of dust and vapors during operation phase.

COMPONENTS OF PROPOSED PROJECT:

- Syrups
- Sachets
- Capsules
- Soft Gelatin Capsule

RAW MATERIAL:

PROCESS FLOWCHART OF RAW MATERIAL:



The list of raw materials is attached as **Annexure-F** with this report.

CHEMICALS:

The list of chemicals is attached as **Annexure-G** with this report. Material safety data sheet to handle all of the chemicals are attached as **Annexure-H**.

MACHINERY:

The list of machinery is attached as **Annexure-I** with this report.

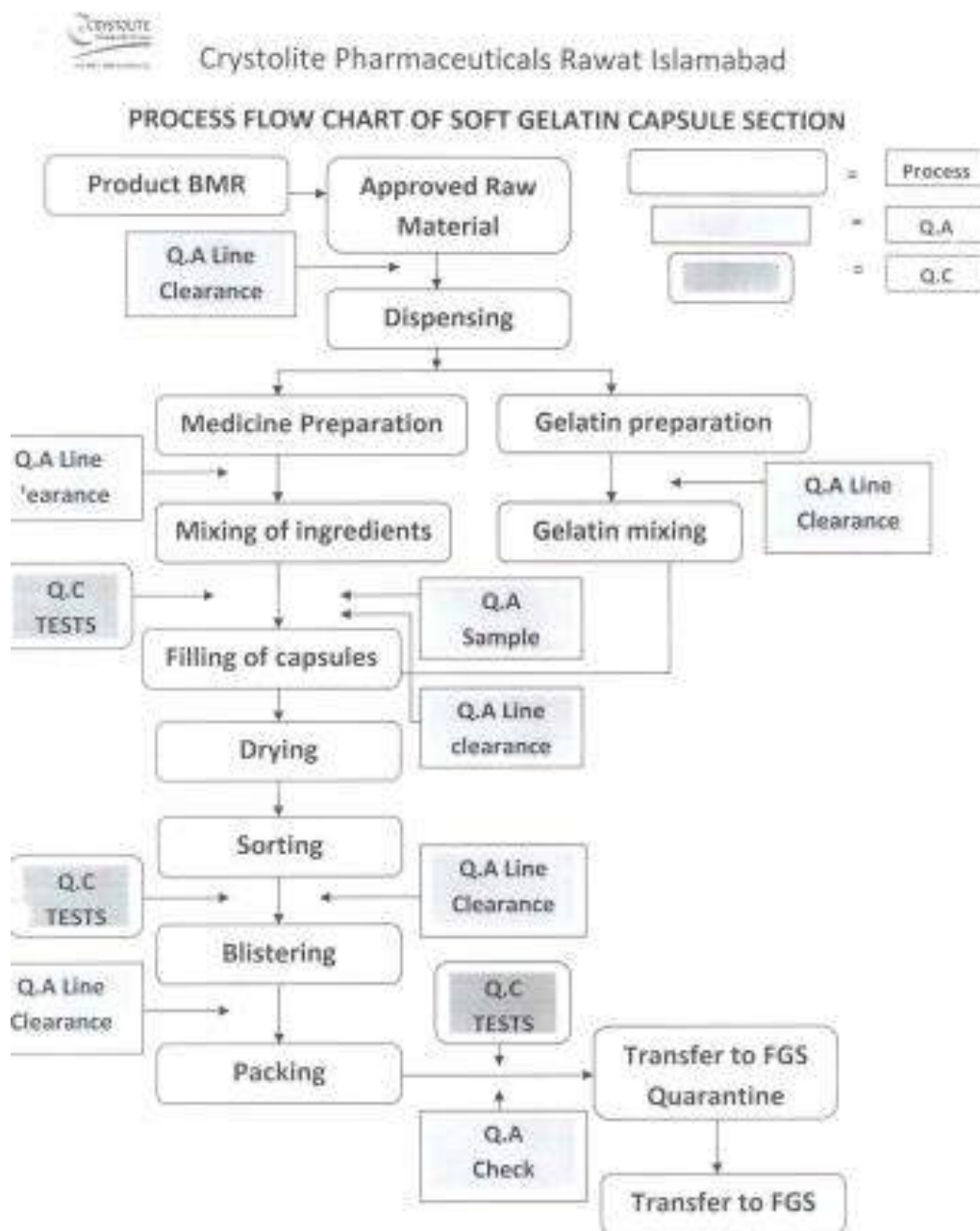
PRODUCT DETAIL:

Product detail of Crystolite Pharmaceuticals is as follows.

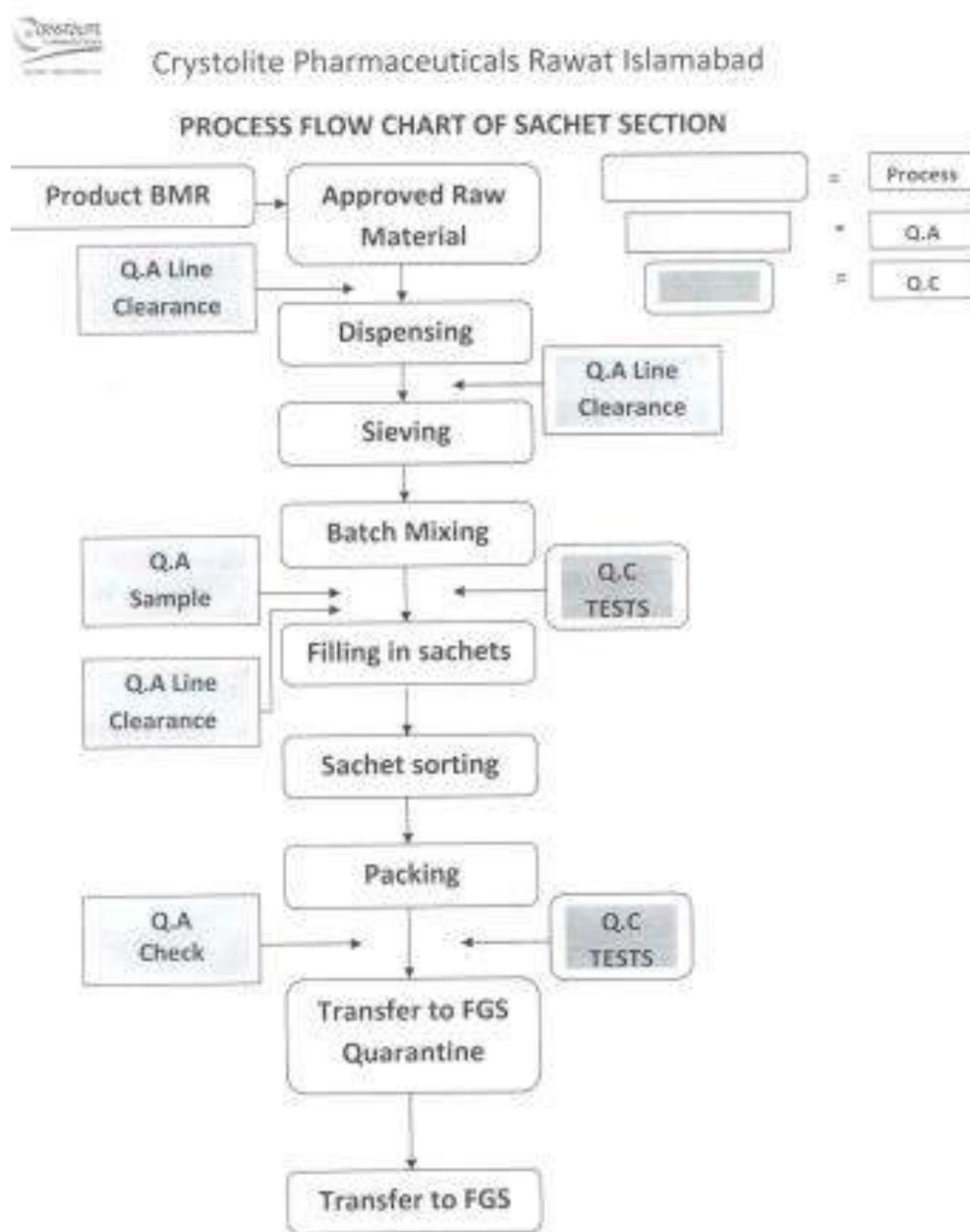
FINAL PRODUCTS
• Syrups
• Sachets
• Capsules
• Soft Gelatin Capsule

PROCESS FLOW OF CRYSTOLITE

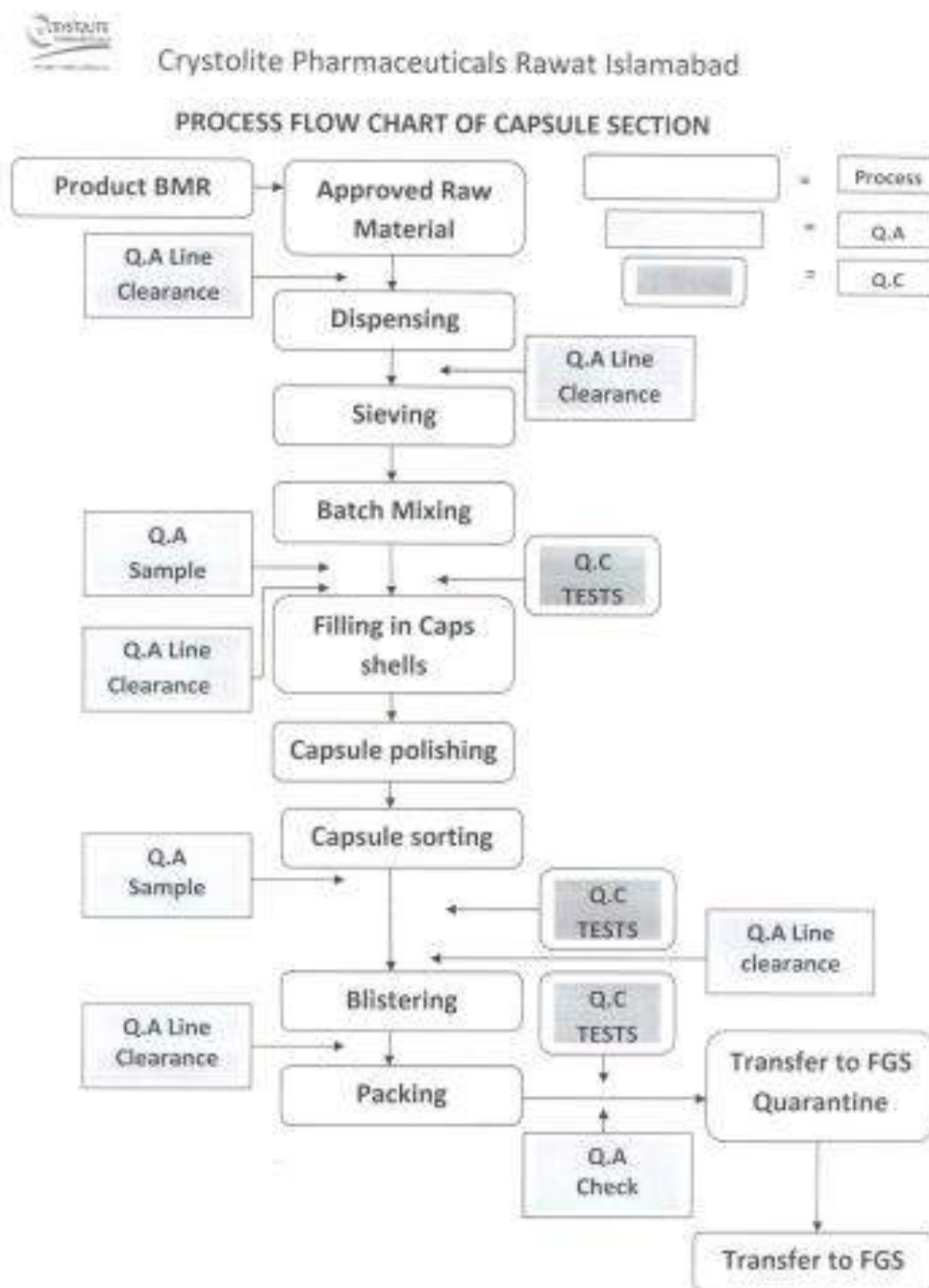
FLOW PROCESS OF SOFT GELATIN CAPSULE:



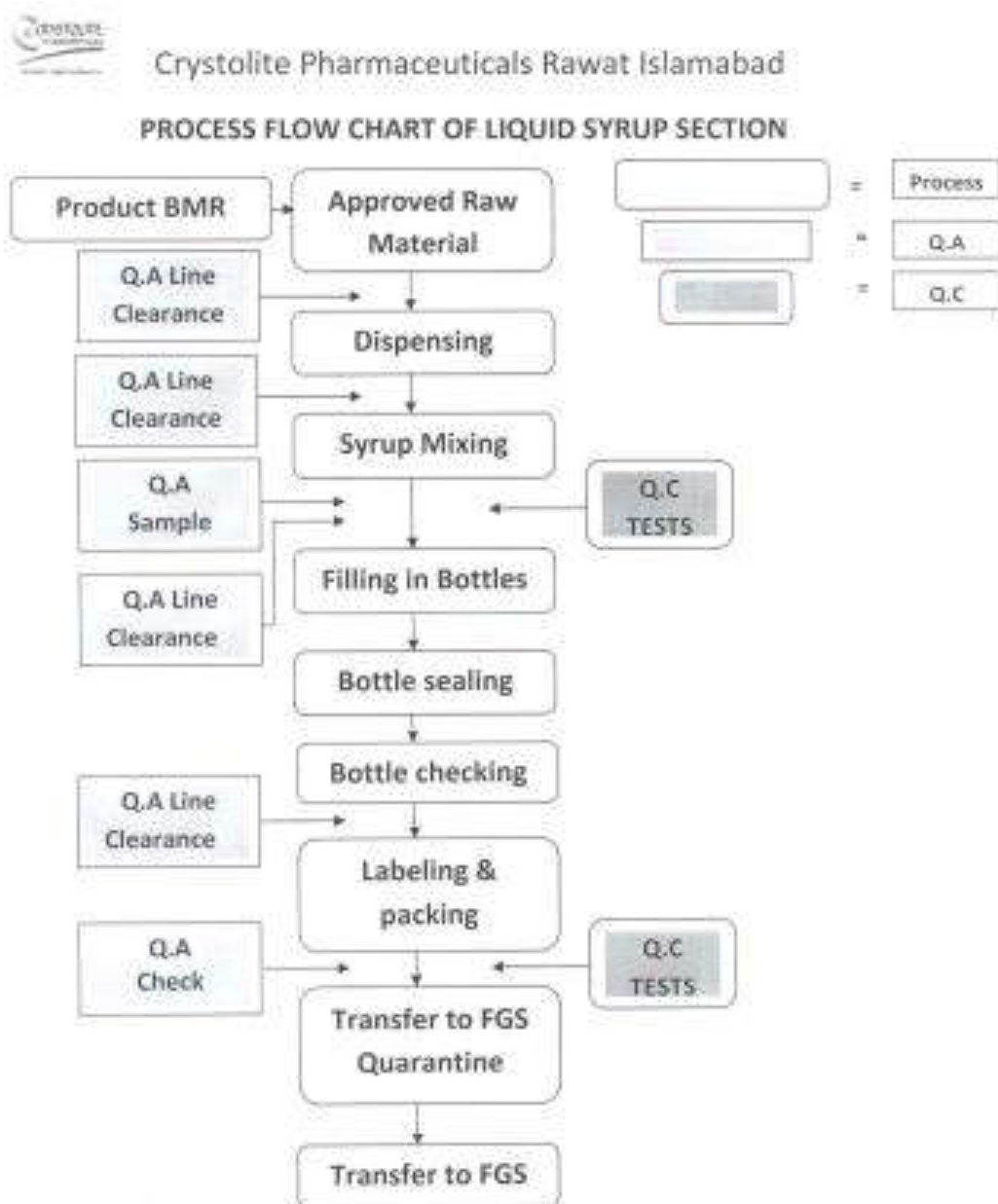
FLOW PROCESS OF SACHET



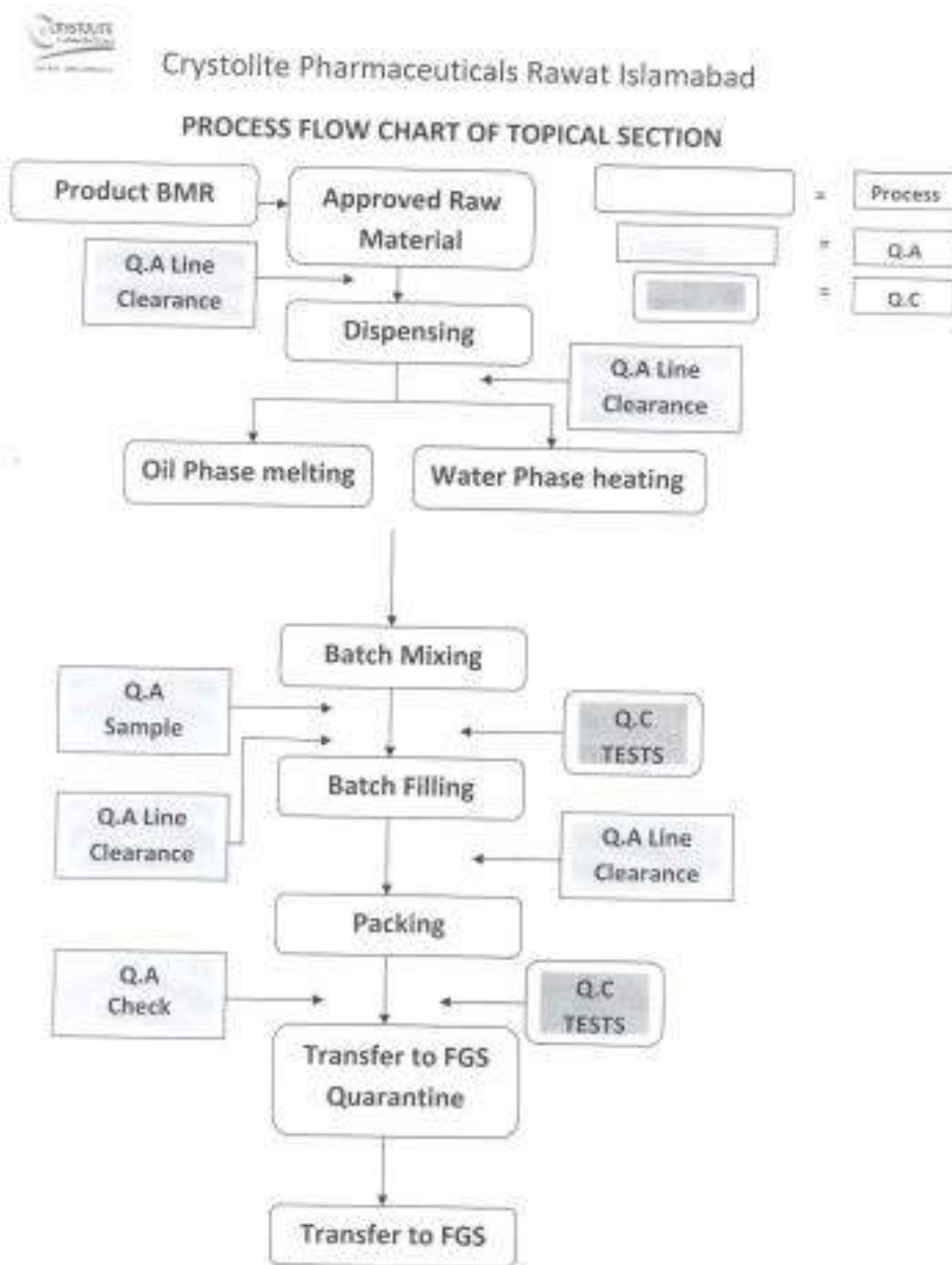
FLOW PROCESS OF CAPSULE:



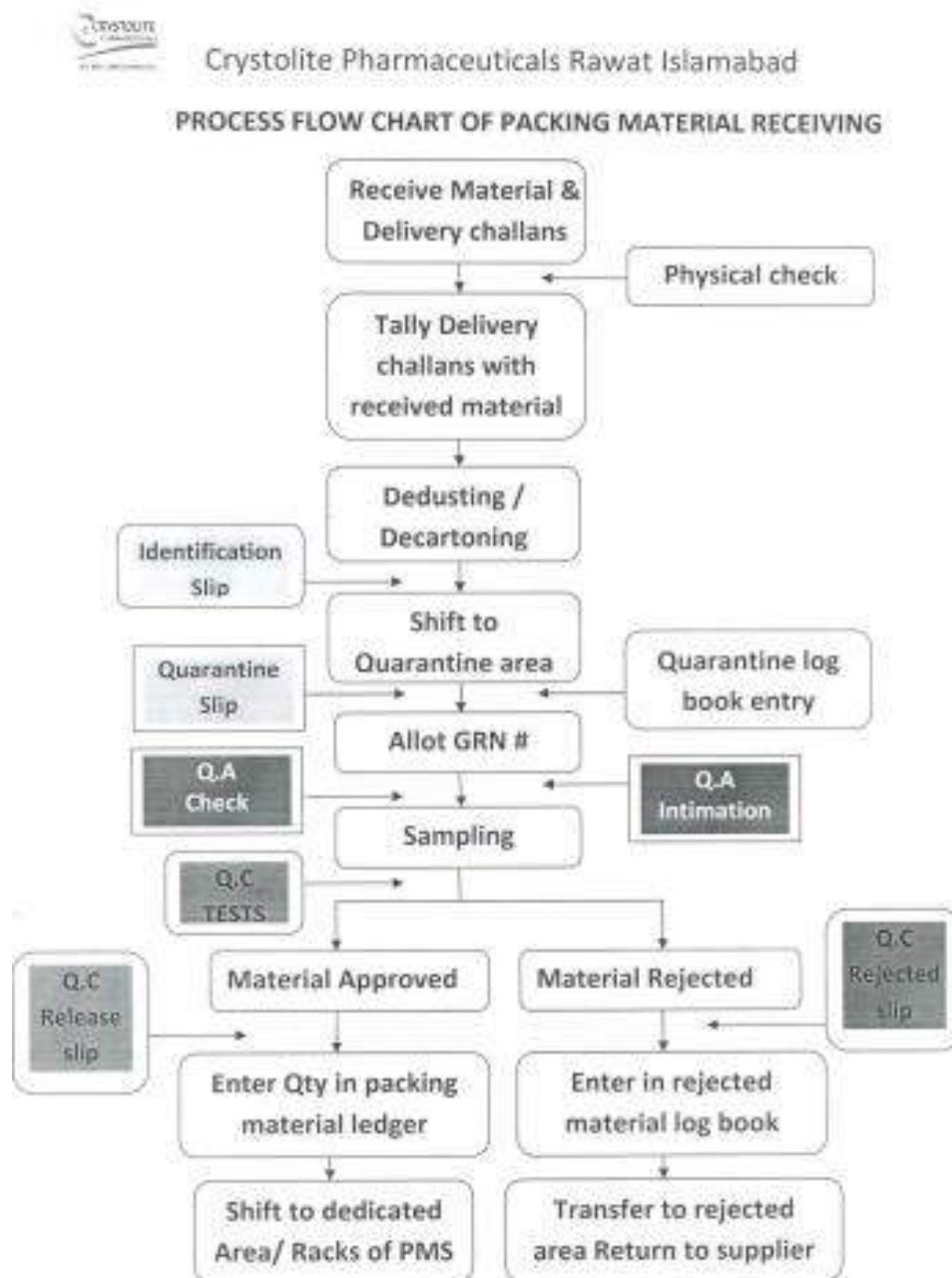
FLOW PROCESS OF SYRUP



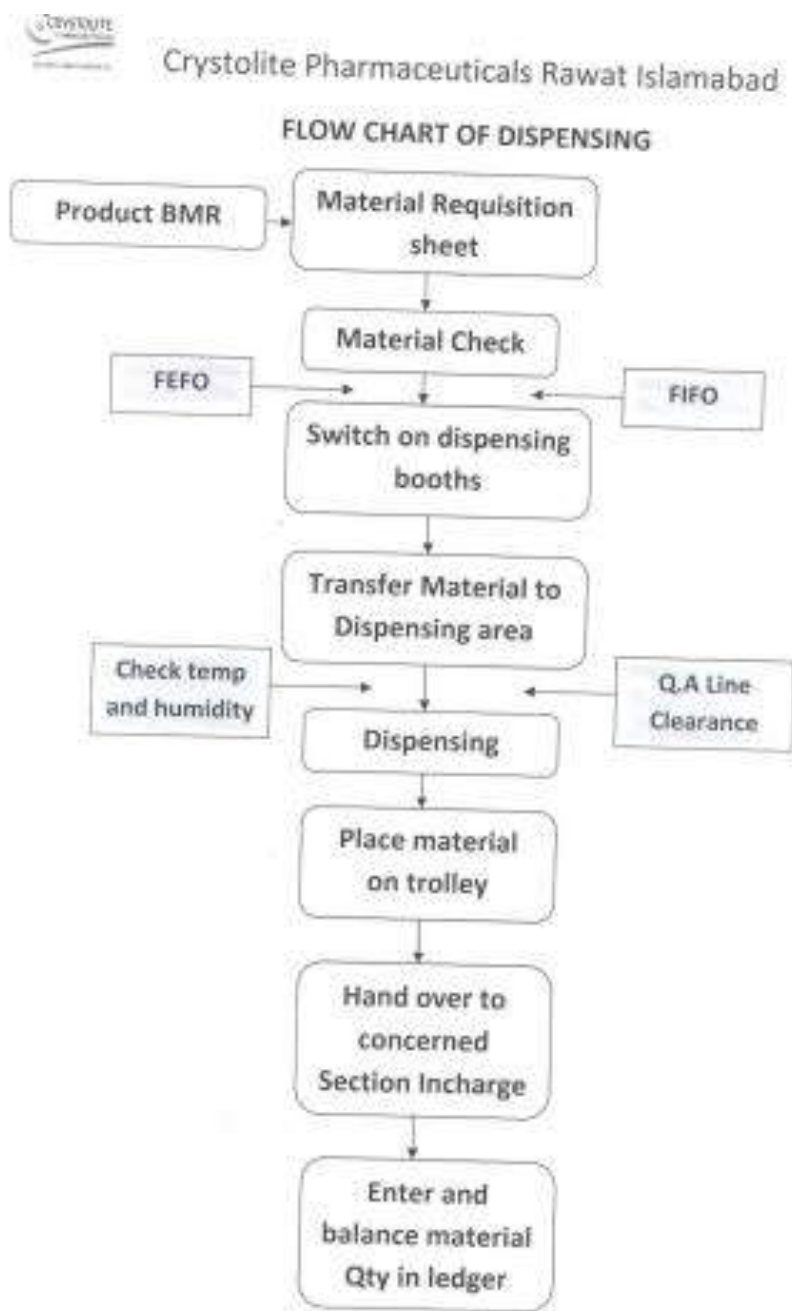
TOPICAL SECTION FLOWCHART



FLOWCHART OF PACKING MATERIAL RECEIVING



FLOWCHART OF DISPENSING



Flow charts of the manufacturing of different products of M/S Crystolite pharmaceuticals, flow chart of raw materials, packing material receiving and dispensing are attached as **Annexure-J**.

WATER REQUIREMENTS:

During construction phase of the project 80 gallons per person per day water required. During the operational phase of the project water will be used according to batch requirement. There

will be the installation of double pass Reverse Osmosis System to meet water requirement. Wastewater will be generated through the liquid production and line washing purposes. Also domestic wastewater will be generated from the site.

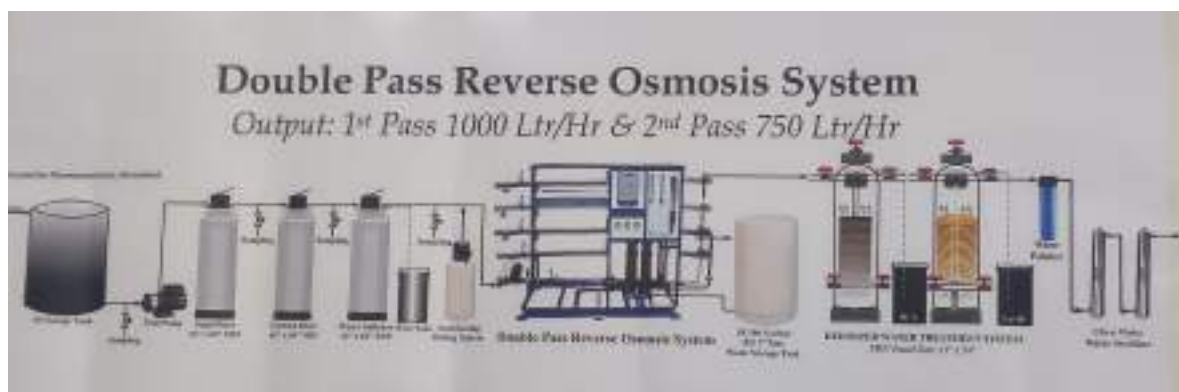


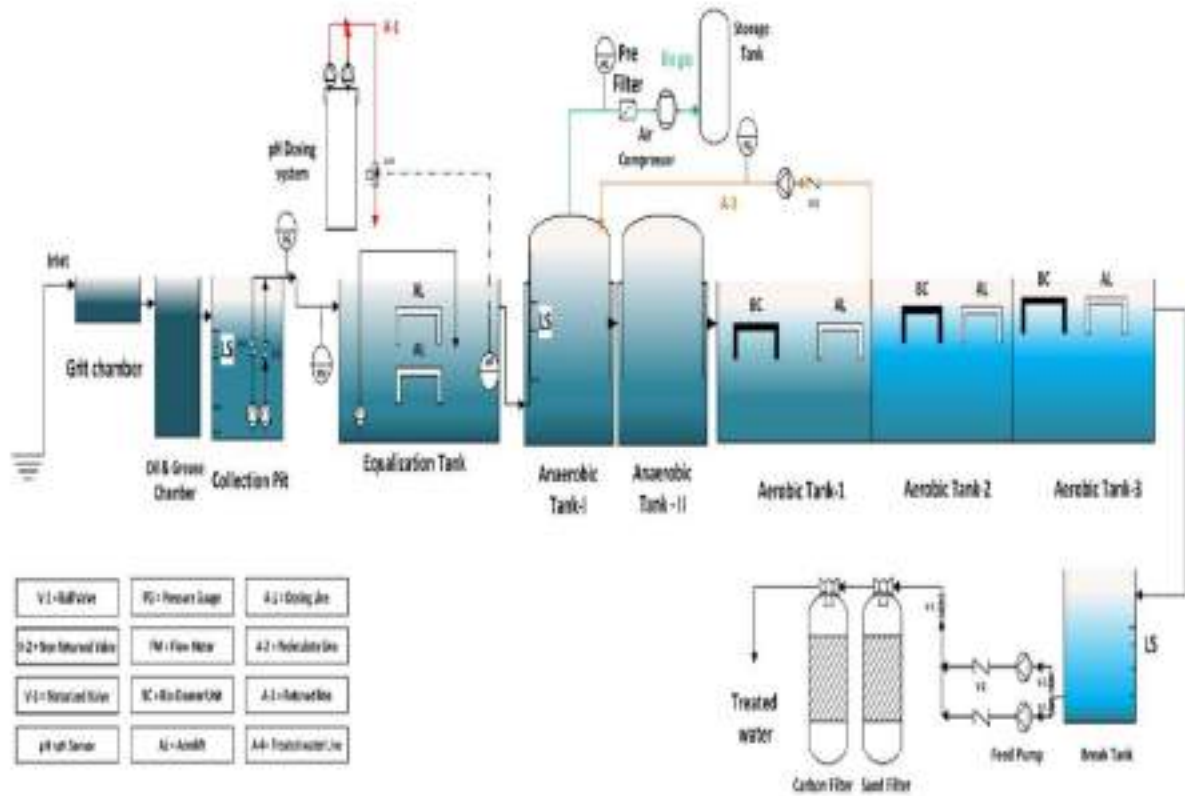
Figure: Double Pass Reverse Osmosis System

WASTE WATER TREATMENT:

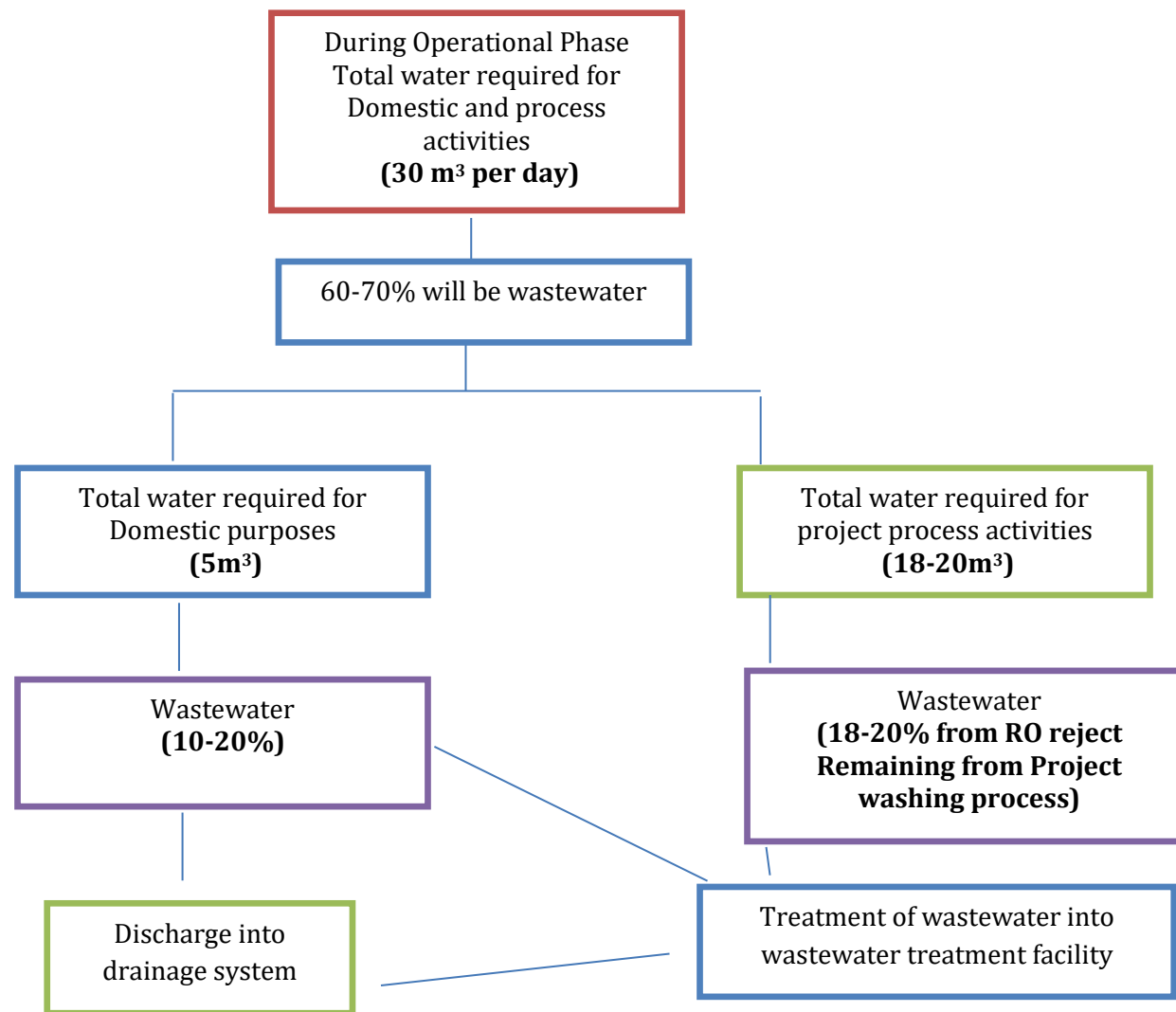
60-70% of the used water will be the waste water which will be treated through the wastewater treatment facility. After treatment wastewater will be disposed of in nearby drain of Rawat industrial estate. M/S Crystolite Pharmaceuticals paying fee to Rawat Industrial Estate. Rawat maintenance slip is attached as **Annexure-N**. And no wastewater will be disposed of into local drain without having treatment.

WASTEWATER DRAIN:

The project site is located at Rawat Industrial Estate. After the treatment the wastewater will be disposed of in the drain. M/S Crystolite Pharmaceuticals paying fee to Rawat Industrial Estate. Rawat maintenance slip is attached as **Annexure-N**.



Estimated Water Balance:



Estimated water balance

SOLID WASTE:

According to an estimate, approx. 560 kg/day domestic and project related solid waste will be produced during the operation phase of the project (based on solid waste generation rates of 0.45 kg/capita/day urban waste generation). Project related waste will be handed over to local contractor. Standard Operating Procedures for factory Waste management is attached as **Annexure-K**.

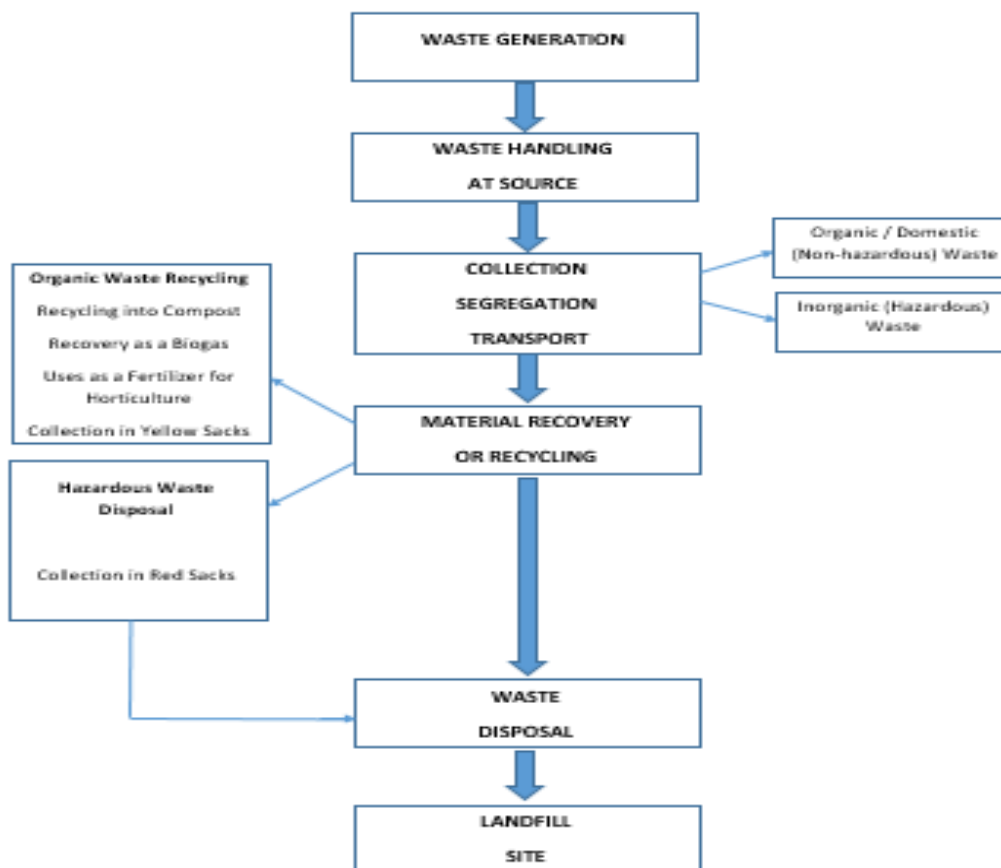
SOLID WASTE MANAGEMENT SYSTEM/PRACTICES

The Solid waste will be managed in proper way by following operations:

1. Placement of separate waste bins for domestic and project related waste in all working halls and designated points.
2. Collection of waste from all the working halls at one designated point by the sanitary workers on daily basis.
3. Collection of waste from designated area and handling to the solid waste contractors for its final disposal.

FLOW CHART OF SOLID WASTE MANAGEMENT PLAN:

SOLID WASTE MANAGEMENT FLOW DIAGRAM



VENTILATION SYSTEM FOR MAINTENANCE OF INDOOR AIR QUALITY:

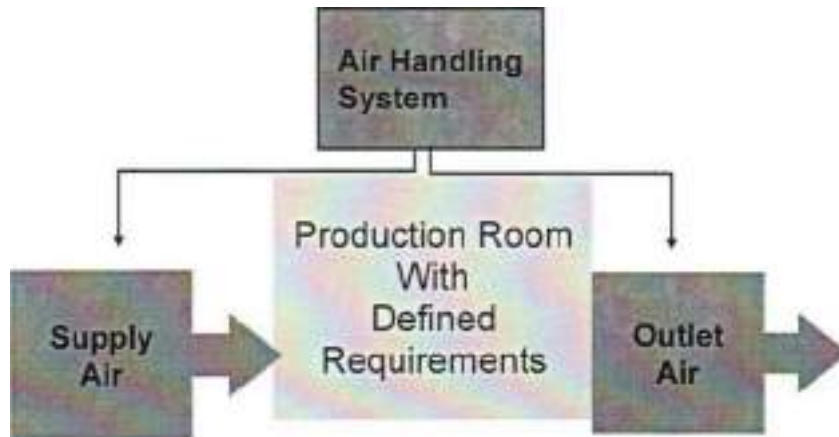
Roof overhangs, window size and placement, and overall building shape is designed in a way to ensure good ventilation. The placement of porches, garages, trees will also be ensured throughout the project activities.

TREATMENT SYSTEM FOR INDOOR AIR QUALITY:

The manufacturing process environment is critical for product quality in pharmaceutical units. It depends on following factors.

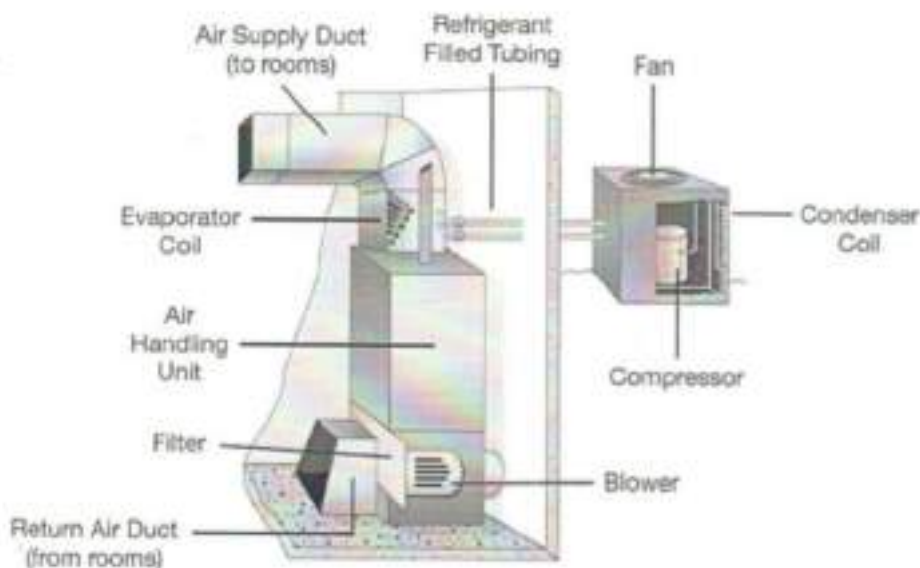
- Light
- Temperature
- Humidity
- Air movement
- Microbial contamination
- Particulate contamination

- Uncontrolled environment can lead to product degradation



HEATING VENTILATION AND AIR CONDITIONING SYSTEM (HVAC):

This system is used to provide heating and cooling services to buildings. HVAC is an important part of residential structures such as single-family homes, apartment buildings, hotels and senior living facilities, medium to large industrial and office buildings such as skyscrapers and hospitals, on board vessels, and in marine environments, where safe and healthy building conditions are regulated with respect to temperature and humidity, using fresh air from outdoors. Ventilation is the process of exchanging or replacing air in any space to provide high indoor air quality which involves temperature control, oxygen replenishment, and removal of moisture, odors, smoke, heat, dust, airborne bacteria, carbon dioxide, and other gases. Ventilation removes unpleasant smells and excessive moisture, introduces outside air, keeps interior building air circulating, and prevents stagnation of the interior air. The proposed pharmaceutical unit will have HVAC system in Production area. It will maintain the temperature and air quality of process area during winter and summer season.



P.P: View of HVAC system diagram

HEPA Filter:

High-efficiency particulate matter arresting or high-efficiency particulate air, is a type of filter. It can remove wide range of airborne contaminants, including fine dust, smoke and vapors. Aluminum filter along with HEPA filter will be installed before air duct with removal efficiency 99.99%. It will capture fine dust, air born contaminants and vapors.



P.P: View of HEPA Filter

MITIGATION MEASURES TO CONTROL THE EMISSIONS OF GENERATORS:

- i) Firstly, usage of the generator made up of latest and environment friendly technology is being ensured at the unit.

- ii) Standard fuel is being used in the generator.
- iii) Proper and regular tuning of the generator will be done.
- iv) Double glazed glass and thick walls canopy of the generators has been installed which will limit the emissions of the noise.

All these measures will ensure the PEQS compliance of generators and emissions will not exceed the limits.

PARKING AREA

Parking area has been made available within the unit for cars, motorcycles, trucks etc.

PERSONAL PROTECTIVE EQUIPMENT:

Following PPEs will be provided to the workers in the unit:

- Dust Mask
- Ear Plugs
- Safety Boots
- Safety Gloves
- Safety Belt
- Helmet
- Goggles

TYPES OF PPES USED DURING OPERATIONAL ACTIVITIES

Protection	Occupational Hazards	PPEs
Head Protection	Falling objects, inadequate height clearance, and overhead power cords	Helmets with or without electrical protection
Hand protection	Hazardous material, cuts or lacerations, vibrations, extreme temperatures	Synthetic or Rubber gloves, leather, insulating material etc.
Eye and face protection	Flying particles, molten metal, liquid chemicals, gases or vapors, light radiation	Glasses, shield protective, etc.
Hearing protection	Noise, ultra sound	Hearing protectors like ear plugs, ear muffs

Respiratory protection	Dust, fogs, fumes, gases, smokes, vapors, oxygen deficiency	Facemasks or air supply
Body protection	Extreme temperatures, hazardous materials, biological agents, cutting and laceration	Aprons, insulating clothing etc. of appropriate materials

The unit will be secured with the presence of security guards round the clock which improves the security of the project site and also in its vicinity.

INDUSTRIES:

Project is present in Industrial area and many industries are present around the unit.

POWER SOURCES AND TRANSMISSION:

Estimated power requirements of the unit are provided by WAPDA.

AVAILABLE FACILITIES

Available facilities at unit are:

- Electric supply from WAPDA
- Solid Management (SWM)
- Line and cellular telephone facilities
- Water supply, sewerage disposal and drainage systems

RESTORATION / REHABILITATION PLAN

All possible precautions will be taken to prevent an untoward incident in terms of life and property losses. The demolition materials will possibly be reused and recycled. All excavated surfaces will be termite proofed.

On completion of the project, the debris is removed from the site in order to maintain aesthetics of the project. All measures will be undertaken for ensuring occupational safety, security and clean environment in the project area. Ornamental trees and flower plants will be planted on inside peripheral of the unit premises to restore the land.

GOVERNMENT APPROVALS REQUIRED BY THE PROJECT:

Project is said project and subject project is a proposed construction of unit for medicinal production unit. Project proponent has committed to obtain all the concern certificates/ approvals from concerned department prior to the operational activity of the project.

CHAPTER # 4

DESCRIPTION OF ENVIRONMENT

This section describes the baseline conditions, which cover the existing Physical, ecological and socio-economic environment of the project as well as study area. Data was collected by reviewing secondary data and field survey.

PHYSICAL ENVIRONMENT

TOPOGRAPHY:

Rawalpindi is a district located in the northernmost part of the Punjab province of Pakistan. Part's of the district form's part of the Islamabad Rawalpindi metropolitan area. Rawalpindi city is the district capital.

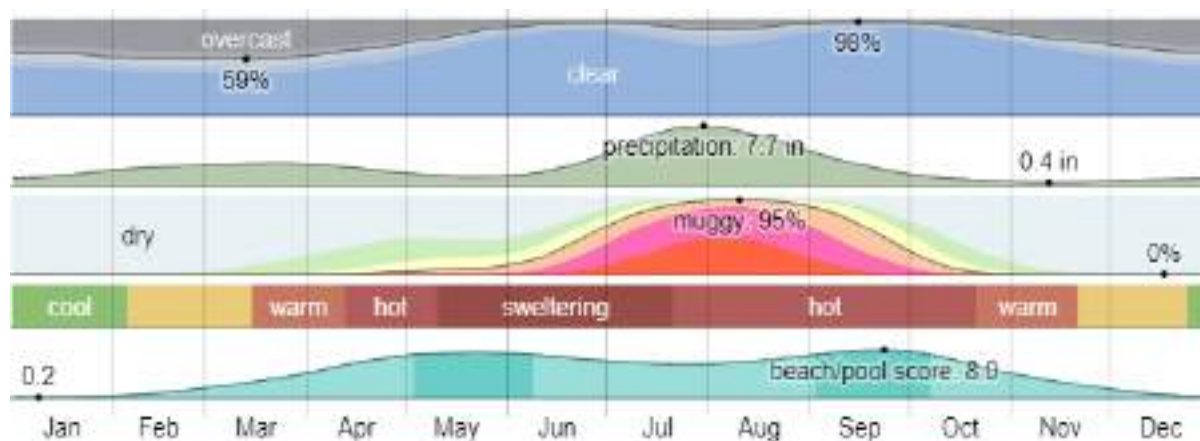
SOILS:

These are mountainous weathered transported deposits (alluvium), which are quite thick and fairly homogeneous in extent. Weathering of soil and rocks are of different types such as chemical and mechanical. The top soil consists of brown, soft to firm clayey silt / silty clay having slight plasticity and contents of dissolved salts. The top layer is likely to extend about 3 to 6 meter below natural ground, where it is underlain by silty fine sand/fine sand. This layer generally continues to deeper depths. These layers of silty clay and sandy gravel may also exist below 10-meter depth.

- (i) Course pebbles with sand or clay.
- (iii) Alluvial deposits of the present river system.
- (iv) An air-borne top layer of silt or clay (loess).
- (v) Conglomerate and loose gravel deposits.

Metrological data of District Rawalpindi including mean relative climate, humidity, rainfall, wind direction and mean wind speed is quoted below:

CLIMATE:

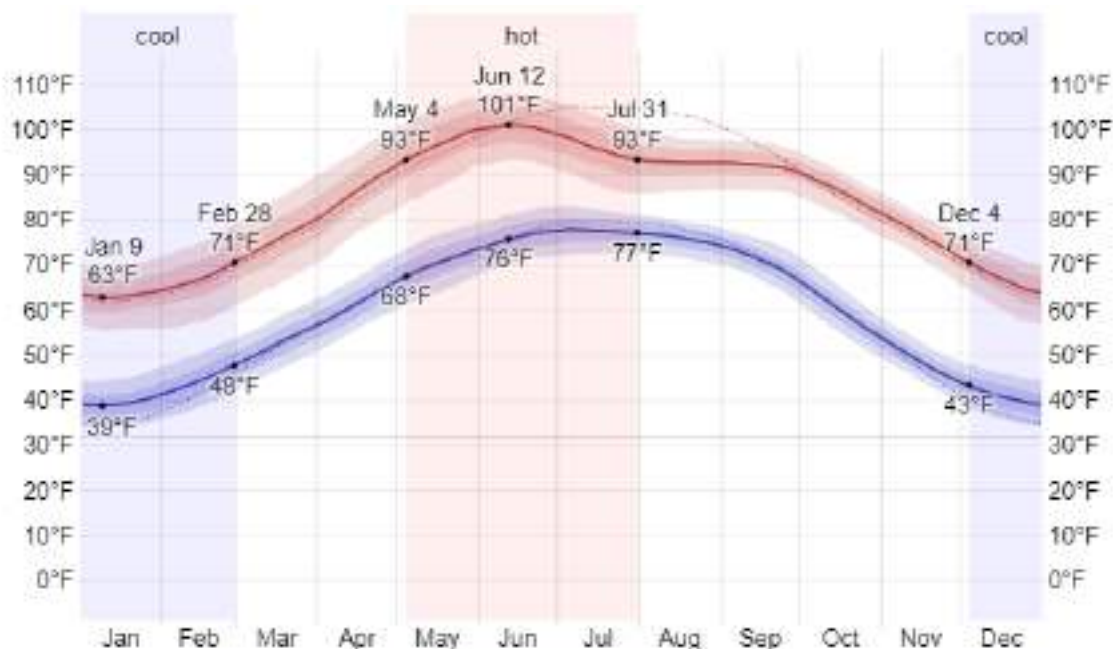


Project site is located in the sub urban area of Rawalpindi. In Rawalpindi, the summers are short, sweltering, humid, wet, and clear and the winters are short, cold, and mostly clear. Over the course of the year, the temperature typically varies from 39°F to 101°F and is rarely below 34°F or above 108°F.

Based on the beach/pool score, the best times of year to visit Rawalpindi for hot-weather activities are from early May to early June and from early September to early October.

The temperature ranges between -1 °C to 46 °C. The coldest month is January when the mean maximum temperature is 17.7 °C and mean minimum 2.6 °C. From February to May the temperature rises at the rate of 5.06 °C per month. The highest temperature is reached in June when the temperature may touch the 46 °C. The average daily wind speed is 1.6 Km/h while average relative humidity remains 59.5%. Rawalpindi receives 94.29mm rain on average monthly basis.

AVERAGE TEMPERATURE IN RAWALPINDI:



The hot season lasts for 2.8 months, from May 4 to July 31, with an average daily high temperature above 93°F. The hottest month of the year in Rawalpindi is June, with an average high of 100°F and low of 76°F. The cool season lasts for 2.9 months, from December 4 to February 28, with an average daily high temperature below 71°F. The coldest month of the year in Rawalpindi is January, with an average low of 40°F and high of 63°F.

RAINFALL:



To show variation within the months and not just the monthly totals, we show the rainfall accumulated over a sliding 31-day period centered around each day of the year. Rawalpindi experiences extreme seasonal variation in monthly rainfall. Rain falls throughout the year in Rawalpindi. The month with the most rain in Rawalpindi is July, with an average rainfall of 6.7 inches. The month with the least rain in Rawalpindi is November, with an average rainfall of 0.5 inches

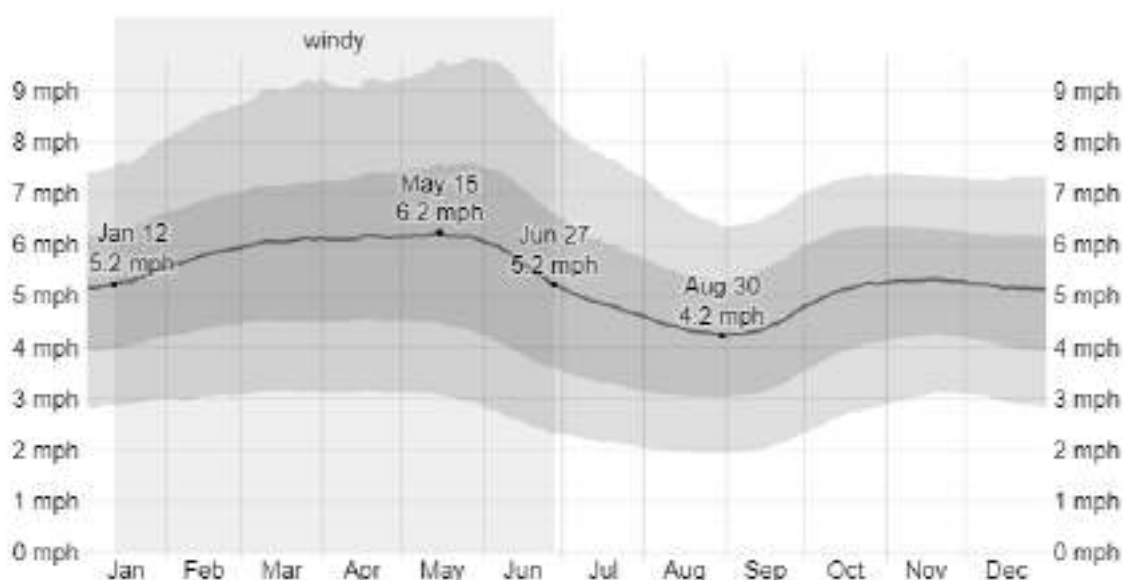
HUMIDITY:



We base the humidity comfort level on the dew point, as it determines whether perspiration will evaporate from the skin, thereby cooling the body. Lower dew points feel drier and

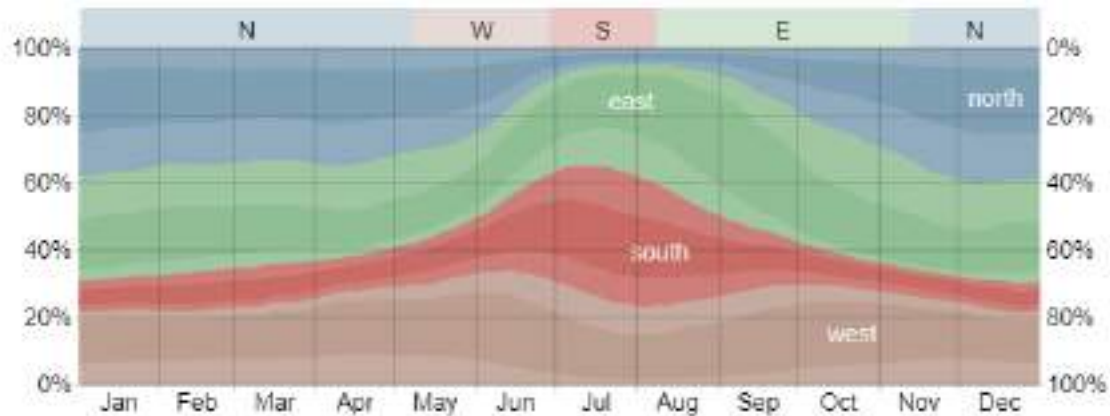
higher dew points feel more humid. Unlike temperature, which typically varies significantly between night and day, dew point tends to change more slowly, so while the temperature may drop at night, a muggy day is typically followed by a muggy night. Rawalpindi experiences extreme seasonal variation in the perceived humidity. The muggier period of the year lasts for 3.7 months, from June 12 to October 3, during which time the comfort level is muggy, oppressive, or miserable at least 24% of the time. The month with the most muggy days in Rawalpindi is August, with 28.9 days that are muggy or worse. The least muggy day of the year is February 5, when muggy conditions are essentially unheard of.

WIND SPEED:



This section discusses the wide-area hourly average wind vector (speed and direction) at 10 meters above the ground. The wind experienced at any given location is highly dependent on local topography and other factors, and instantaneous wind speed and direction vary more widely than hourly averages. The average hourly wind speed in Rawalpindi experiences mild seasonal variation over the course of the year. The windier part of the year lasts for 5.5 months, from January 12 to June 27, with average wind speeds of more than 5.2 miles per hour. The windiest month of the year in Rawalpindi is May, with an average hourly wind speed of 6.2 miles per hour. The calmer time of year lasts for 6.5 months, from June 27 to January 12. The calmest month of the year in Rawalpindi is August, with an average hourly wind speed of 4.4 miles per hour.

WIND DIRECTION:



The predominant average hourly wind direction in Rawalpindi varies throughout the year. The wind is most often from the west for 1.7 months, from May 8 to June 28, with a peak percentage of 34% on June 14. The wind is most often from the east for 3.1 months, from August 8 to November 12, with a peak percentage of 43% on September 6. The wind is most often from the north for 5.9 months, from November 12 to May 8, with a peak percentage of 38% on January 1.

AIR QUALITY:

The project site is located in the sub urban area of district Rawalpindi. The major sources of air pollution in the area are vehicular traffic and the industries located in main city.

To record the baseline ambient air quality of the project area, three samples were collected at different location to observe the level of CO, SO₂, NO₂ and Particulate Matter (PM₁₀). The results of the samples are within the NEQS limits.

NOISE LEVEL:

Major sources of noise generation are animals, birds and vehicular traffic (particular loaded and unloaded truck, van) along the main road. Noise levels were monitored at different location of the project site. The noise levels are falling in the range of 42-72 dB.

GROUND WATER:

Underground water is available in large quantity and its quality is very good. The underground water is supplied by pumping system (motor pump, tube well, hand pump) to

the residents of the area. The underground water is of good quality and all its parameters being tested are within the WHO guide lines and the water is fit for drinking purposes.

EECOLOGICAL ENVIRONMENT:

FISHERIES:

The project area is free from any commercial fishing activity. There are no lakes, even natural water ponds in the vicinity. Therefore, Fishery or any worth mentioning aquatic biology in this area is out of question.

BIODIVERSITY:

Natural capital of a country mainly includes all of the country's wilderness areas and scenic landscapes, including also with their associated flora and fauna. Pakistan has a total of nine major ecological zones. The contribution of the "Natural Capital" is recognized at three distinct levels: species, genera, and communities (habitat and ecosystem) both collectively and within each level, the range or variety of the resources are referred to as the "Biological Diversity". The term has relevance for each of Pakistan's administrative units district, province, and particularly country. The more the number of species, genera, and habitats and ecosystems present within these units, the greater is said to be the biodiversity. The biodiversity of the area, with this background, is discussed as under.

FLORA AND FAUNA:

The wildlife of the district includes foxes, boars, jackals and wild cat. Among the birds there are usually partridges, pigeons, doves, tillers, lal means, bias, parrots, quails, pochards, and mallard.

The flora of the district is of varied character and is typical of a tract well suited for the growth of vegetation. The soil is fairly rich and deep and the spring-level is high enough for the roots to absorb adequate moisture. Different types of pines and spurs are frequently seen in the project area.

In the plains, the trees most frequent are Shisham (*Dalbargia sissoo*), citrus, Mascot, (*Ficus mircofila* (Pepli), *Ficus Religeousa* (pepal), *Ficus Banglensis* (Bohard), Toot (*Morus alba*), *Bauhinia variegata*, *Celtis eriocapra*, *Pyrus pashia*, *Punica granatum*, *woodfordia floribunda*,

Zizyphus mauritiana, Carissa spinarum, Hetropogon contortus, Aristada cyantha, Drek (Molia simper virens), Phulai, (Acacia modesta), Ber (Zizyphus jujaba), and Kikar (Acacia arabica) etc. A conspicuous species of grass is Dab (Amuricatus). There is scattered vegetation of bushes. These bushes are ever green and have deep roots, as the soils are mostly poor in humus and thus relatively desiccated and dry, at least in the upper layer. The roots go deep for moisture.

The other vegetation that grows scattered is Myrsine African, Carissa opaca and Acasia modesta. The shrubs that also grow in lesser density are Ziziphus nurnmufaria, Sagretia brandrethiana, Adhatoda vasica. Grasses tayer, which usually grows in depressions or on relatively moist soil under shade comprises of Chrysopogon aucheri, and Andropogon.







Figure 2: Pictorial view of Ecological survey

During the survey of environmental consultant, it is observed that the project area have various species of trees (especially citrus trees, Ficus species trees and *morus alba* trees) and shrubs. Few plantations cover will be removed for landscaping and development purpose. The proponent will plant 3 trees in return of cutting 1 tree. Beside this proponent has allocated area for plantation.

RARE OR ENDANGERED SPECIES:

There are no game reserves or protected lands/areas or endangered or rare species in the area within the range of 4-5km from the project site. But there are different organizations are working for the protection of endangered species of the area in surrounding major cities. However, there is no potential impact of the project on endangered and threatened species.

SOCIOECONOMIC ENVIRONMENT:

POPULATION AND COMMUNITIES:

Project site is present in the District Rawalpindi. The surrounding area of the project site has a population of about 70,000. There is facility of primary Schools and colleges and Engineering universities in nearby locality. Beside this most of universities are present in the neighbor major cities like Rawalpindi and Islamabad. Well medical facilities are available to the public. Both private and govt. hospitals are present in surrounding of the project site.

QUALITY OF LIFE VALUES:

SOCIOECONOMIC VALUES:

Majority of the residents of the area belong to middle class. Small proportion of people is among the affluent class. Some people earn their livelihood while performing private jobs, carrying out business on small and large scale and even running very small shops etc.

Importance of educational values is highly found. Consequently, the people send their children to educational institutions and try to get them educated to the extent their financial means permit them. The people share with each other the social, cultural and economic values of life. To a greater extent there is harmony towards collective interests among the people.

MAIN PROFESSIONS AND OCCUPATIONS:

a) OFF-FARM ACTIVITIES:

Off farm activities constitute dominant sector of the local economy. Most of the people were reported as engaged in service sector; employment with government and non-government organizations. Majority of people is employed mostly in clerical and low status jobs. Part of economically active population carries out daily wage work, wherever available, followed by an insignificant number of people engaged in commercial/business activities, such as general/grocery stores and public call offices.

b) ON-FARM ACTIVITIES:

Farming and livestock management is the second major sector of local economy. Land holding, though very small, is predominantly used for agriculture farming. Major crops grown in the area include wheat, maize etc.

PUBLIC HEALTH:

As far as medical facilities are concerned, area has medical facility. There are number of hospitals i.e. civil hospital, HMC hospital and dispensaries with a single doctor, few private clinics are present there but most of the people travel in the surrounding cities for medical treatment in serious conditions.

RECREATIONAL RESOURCES AND DEVELOPMENT:

The project area has not any private recreational facilities but the attached major cities have many public places for the purpose of recreation.

AESTHETIC VALUES:

Like the general trend among the citizens of area, most of the people have low awareness about environment. Even then, some people take cleanliness and neatness of the environment lightly. Some people throw municipal solid wastes (MSWs) on the streets. Sense of personal responsibility to keep the environment clean as good citizens is even now lacking among a few people.

FAMILY SYSTEM:

(a) NUCLEAR FAMILY SYSTEM:

Some families are living in nuclear family system. It means that husband, wife and their children living in one home.

(b) EXTENDED FAMILY SYSTEM:

Extended Family System is common in the community; in which father, mother, their son and daughter in law living with their children in one home.

(b) JOINT EXTENDED FAMILY SYSTEM:

They adopted joint extended family system from their forefathers; in which Grandfather, Grandmother, Father, Mother, Son, Daughter in law and their children live together in one home.

ARCHAEOLOGICAL AND HISTORICAL TREASURES:

Archaeological or historical treasures within the project site are not available in the vicinity of project site.

CULTURAL VALUES:

There is blend of poor and elite class among the residents of the project site. One can see a mixture of modern and old cultural values. Younger generation is vastly adopting modern cultural values of the affluent society of nearby mega cities like Islamabad and Rawalpindi. Elderly people are well respected and they even now play a decisive role in decision making in family matters. The liberal independence is also dominating now days.

CHAPTER # 5

SCREENING OF POTENTIAL ENVIRONMENTAL IMPACTS & THEIR MITIGATION MEASURES

The following chapter describes the overall possible impacts of project on the physical, biological and socioeconomic environment because of operational phases and mitigation measures to minimize the significance of the possible impacts up to an acceptable level. The anticipated impacts related to project location, design, and operational phases have been assessed and mitigation measures are provided accordingly.

IDENTIFICATION OF ALL IMPACTS:

All the impacts related to the subject project due to the project location, during the operational phase have been identified and their mitigation measures have been suggested in Chapter # 4, Screening of potential environmental impacts and mitigation measures.

METHODOLOGIES FOR IMPACT IDENTIFICATION:

The methodology adopted for impact evaluation includes the Project Impact Evaluation Matrix.

PROJECT IMPACT EVALUATION MATRIX

The impact Evaluation matrix was developed by placing project activities on x-axis and different environmental parameters likely to be affected by the project actions grouped into categories i.e. Physical, Biological and Socio-Economic Environment. For the impact assessment, project impact assessment matrix is used by dividing the project action into different phases operation phase. A project impact evaluation matrix is attached in next section of this chapter.

The evaluation of impacts has been carried out on the basis of developing matrix, in which impacts have been rated on the basis of their significance. For rating impacts significance following criterion has been developed;

NA – Not Available

O – Insignificant (No or minimal impact)

LA – Low Adverse (Short term, reversible or less damage to environment)

MA- Medium Adverse (Long term reversible damage to environment)

HA – High Adverse (severe irreversible adverse damage to the environment)

LB – Low Beneficial (Short term benefits or less beneficial to the environment)

MB – Medium Beneficial (Long term benefits to environment)

HB – High Beneficial (Continuous benefits to environment)

	Physical Environment							Biological Environment		Socio-Economic Environment								
Environmental Component Project Activities	Topography & Drainage	Soil Quality	Landscape	Surface water quality	Ground water quality	Air quality	Noise	Flora	Fauna	Agricultural Land	Health & Safety	Disruption of Public Utilities	Employment	Population Disturbance	Social Disorder	Cultural Values	Traffic Management	
Transportation of raw material/ products	MA	MA	MA	MA	O	MA	HA	LA	MA	O	HA	LA	B	MA	LA	O	HA	
Production process	O	O	O	HA	MA	MA	MA	O	O	O	HA	HA	HB	O	O	LA	O	
Washing process	O	O	O	LA	HA	O	O	LA	LA	LA	LA	HA	B	O	O	O	O	
Operation of boilers	O	O	O	LA	HA	MA	MA	O	O	O	HA	HA	HB	O	O	O	O	
Operation of generators	O	O	O	O	LA	HA	MA	O	O	O	HA	LA	HB	O	O	O	O	
Water consumption	LA	O	LA	HA	HA	O	O	LA	LA	LA	LA	HA	B	LA	O	O	O	
Wastewater generation	HA	MA	MA	MA	MA	LA	O	MA	MA	MA	HA	LA	B	LA	LA	O	O	
Storage of raw materials/ dyes	O	O	O	O	O	O	O	O	O	O	LA	O	B	O	O	O	O	

Social activities	O	O	LB	B	B	B	B	B	B	HB	HB	B	H B	HB	HB	HB	O
Public welfare	O	O	B	B	B	B	B	B	B	HB	HB	HB	H B	HB	HB	HB	LB
Economic activities	LB	O	B	B	B	B	B	B	B	B	HB	B	B	B	B	B	LB
Employment	O	O	O	O	O	O	O	O	O	O	B	B	H B	B	B	B	LB
Infrastructure improvement	LB	M B	HB	B	B	B	B	HB	LB	HB	HB	B	H B	B	B	B	B

Legend:

O=Negligible/No impacts

B=Beneficial

LA=Low Adverse

MA=Medium Adverse

HA=High Adverse

IMPACT ANALYSIS AND PREDICTION:

In order to evaluate the socioeconomic and environmental impacts, filed surveys are extremely essential. In addition to the surveys at the preliminary stage, consultation with the community and their active participation plays a vital role in successful implementation of the project. For the impact analysis and predictions following methods were adopted:

CONSULTATIONS/ CASE STUDIES:

To study the impacts of the project on physical and biological environment, site visits were conducted by the environmental practitioners and experts and possible physical and biological impacts which may arise due to the subject project were identified through consultations and case studies and their mitigation measures were suggested accordingly.

MEETINGS:

For the identification of the social impacts of the project, meetings and group discussions were held with the local people, stakeholders, nearby residents and passerby because social acceptability of the project and the area is a key to success. Consultation with the stakeholders is a tool for managing two-way communication between the project proponent and the affected public. Its goal is to improve decision making and built understanding by actively involving individuals, groups and organizations, which have stake in the project. This involvement increases project's long-term viability and enhances its benefits to locally affected people and other stakeholders.

To identify the different types of stakeholders and ascertain their perceptions about the project, an initial environmental examination was conducted. Informal group discussions were also held as an additional tool for obtaining feedback from the stakeholders that are being discussed in the following.

The EIA team carried out public consultations at various locations around the Project Site. The stakeholder's consultation during this phase of the work targeted the project area, administrative and private offices, Govt. offices, shops, etc. near the Project area:

- ✚ Selection of the stakeholders for consultation, reconnaissance of the project site and initial discussions with the neighboring factory workers, villagers, shopkeepers, drivers etc.

- ✚ Environmental consultants and social specialists and documenting the opinions of the stakeholders expressed during the meetings etc.

CHARACTERISTICS OF IMPACTS

ENVIRONMENTAL IMPACTS DUE TO PROJECT LOCATION

Project is present in the industrial area of the District Rawalpindi. No nearby human settlement exists within the radius of 500 meter. Unit is establishment of medicinal formulation unit, and unit/ area does not fall in the category of sensitive area and no environmentally sensitive localities exist within radius of study area. The only issue which can arise due to the location of the subject project could be the issue of traffic congestion due to transportation of the construction material at the project site. If the project proponent maintains HSE conditions and comply with the PEQS limits than, there will not be any significant impacts of the project on the environment.

If the mitigation measures are effectively implemented, the residual impact of the Subject project activities on the area's geophysical environment is expected to be insignificant.

Impact significance: Low or may be positive

Nature of impact: Direct

Duration: Long-term

Timing: Operation phase

Reversibility: NA

Likelihood: Low (unlikely),

Consequences: Mild or may be positive

MITIGATION MEASURES FOR LOCATION PHASE IMPACTS

- Project site have good road infrastructure and efficient road infrastructure already exists there that is used currently to access the site and there is no issue of the road congestion due to the wide, good and paved road.
- Location can be considered as the positive impact due to utilization of the product in the same District.
- The project has provided the jobs to the residents as well as to those from the suburban areas.

ENVIRONMENTAL IMPACTS DUE TO THE PROJECT DESIGN

The current project is present in Rawat industrial estate. Area for parking, waste water treatment facility and solid waste management will be reserved within unit. Firefighting plan, health & safety plan, tree plantation plan, emergency response plan will be incorporated during the design phase of the project.

RESIDUAL IMPACT:

The residual impact of project activities for the land acquisition & resettlement of the area is expected to be insignificant.

The residual effects are summarized below:

Nature of impact: direct

Timing: Planning stage

Duration: not applicable

Likelihood: Nil

Consequences: no change

Impact significance: Not significant

MITIGATION MEASURES:

If any resettlement involve, proponent must consult the affected persons and incorporate their interests and demands.

CHANGES IN LAND USE:

The current land use of the area is mainly industrial. Project is expected to increase land use value particularly near the main road creating easy economic and employment opportunities for locals.

RESIDUAL IMPACT:

The residual impact of project activities on land use of the area is expected to be insignificant.

The residual effects are summarized below:

Nature of impact: direct

Duration: not applicable

Likelihood: Nil as it is not involving any constructional activity that may cause change in land use

Consequences: no change

Impact significance: Not significant

ENVIRONMENTAL IMPACTS DURING THE CONSTRUCTION PHASE

Impacts related to the construction phase of the subject project are discussed below

IMPACTS ON THE PHYSICAL ENVIRONMENT

SOIL EROSION AND POLLUTION

There is a possibility of soil erosion and pollution to occur during construction phase of the project. The clearing of vegetation could lead into soil erosion when the cleared land is exposed to natural agents such as wind and surface run-off. Removal of top soil after site clearance by agents such as wind, rain water, and surface run off is a likely action to occur. Similarly, accidental oil spills from construction equipment and discharge of wastewater to the environment might accelerate soil pollution to some extent. Oil spills may infiltrate into soil causing soil pollution and later water pollution during rainy season.

However, this impact is localized around machinery, maintenance areas or garage and areas of concentrated activities. Severity of impact is localized with low intensity due to the nature of project, which shall require minimum number of people during construction and shall not require heavy construction equipment. It is expected that the impacts will be low, local, and they will occur mostly during the construction stage (short term).

AIR POLLUTION

Air pollution is quite likely to occur during construction phase. This is due traffic and other equipment using fossil fuels that release hydrocarbons and other gases including carbon dioxide, nitrous oxides, Sulphur oxides, and particulate matters which may pollute the air. Likewise, activities like land clearing, vehicle movement, excavations for buildings

foundations, construction drive ways and landscaping may generate dust especially during the dry season.

Other sources of air pollution will occur due to decomposition and/or burning of the cleared vegetation and dust from gravel drive ways. The level of air pollution originating from the above-mentioned sources are expected to be low, localized and short term. No serious impacts are expected on people and the environment as whole.

SURFACE WATER POLLUTION

No surface water entity i.e., stream, canal, river is present in the vicinity of the subject project so there is no impact of subject project on the surface water.

IMPACTS ON BIOLOGICAL ENVIRONMENT

IMPACTS ON FLORA

The clearance of most vegetation during construction to leave space for construction of proposed unit and other building facilities and access roads will bring negative impacts to flora population. Moreover, direct exposure to nitrous oxides (NO_x) may cause growth inhibitions in plants to some extent. No special plant species of international conservation importance was recorded at proposed site. The impacts are therefore considered of low significance.

IMPACTS ON FAUNA

The nature of the site has not attracted several organisms to find refuge in the area although some including different types of birds, reptiles, amphibians and invertebrates are found. The clearance of vegetation and presence of noisy machinery, trucks and workforce will create unfavorable environment for most of these organisms while crawling organisms will eventually vanish following construction of paved surface.

However, the temporary nature of the construction activities will result in impacts of short-term duration and therefore the impact is considered of low significance.

IMPACTS ON SOCIOECONOMIC ENVIRONMENT

WORKERS ACCIDENTS AND HAZARDS DURING CONSTRUCTION

Construction workers are prone to accidents resulting from construction activities. These accidents may have acute or chronic impacts depending on nature, severity and intensity. In this regard, construction and mobilization activities of the proposed unit could result into accidental injuries and hazards, etc. which could negatively impact the workforce.

Because of the intensive engineering and construction activities including erection and fastening of roofing materials, metal grinding and cutting, concrete work, steel erection and welding among others, construction workers will be exposed to risks of accidents and injuries. At times, such injuries may be from accidental falls from high elevations, injuries from hand tools and construction equipment cuts from sharp edges of metal sheets and collapse of building sections among others.

VIBRATION AND NOISE

The level of noise and vibration are likely to increase during the construction phase. The noise will be mainly come from vehicles and equipment operation during construction activities as well as people working on the project construction. This is a short-term impact and it will be felt mostly around construction sites and its peripherals.

There will be no drilling activities or involvement of heavy or high noise machinery. For residential areas located within 20km from the Project site boundary, it is predicted that the construction phase and operation of the proposed project will not pose any significant and the annoyance level is within the “no to little” impact category.

Considering technological advancement in construction industry, it is anticipated that machinery and equipment to be used during construction will be modern, versatile, and quieter than the old ones. It is also likely that they will require fewer numbers of operators reducing noise from workers. Therefore, the levels of noise and vibrations are anticipated to be within the tolerable limits, short term and localized. In view of the above and the fact that construction will concentrate on non-residential area, no significant impact is anticipated and the impact can be highly mitigated.

EMPLOYMENT OPPORTUNITIES

On the other hand, the proposed project will have, during construction phase, potential positive impact to the local community through provision of employment. It is expected that maximum people will be employed during construction phase. Employment will be in form of managers, skilled labors as well as unskilled laborers. Therefore, apart from employment benefits accruing to local people other national and international experts are likely to be employed by the project especially at senior positions.

INCOME GENERATION AMONG SUPPLIERS

During construction phase, the proposed project plan to source most construction materials from local and/or national sources including cement, iron sheets, steel bars, pipes, etc, from local shops. This demand therefore, will create market for local people and/or elsewhere in the country engaged in supplying construction materials leading to significant positive economic benefits to suppliers on short term basis.

IMPACTS ON SECURITY

The presence of laborers and expensive construction equipment, machinery and materials in the sites could potentially pose a security risk at the project site. Furthermore, offenders may capitalize on increased movement during construction and anonymity created by the construction activities to carry out criminal activities in the site and surrounding areas. This impact is likely probable due to low security measures from the fact the site is slightly far from police station(s) that could otherwise prevent criminal activities around the project site.

Accordingly, the impacts on the area's security are considered to be of medium significance. Therefore, appropriate security measures should be provided at the site through fencing, security checks/screening of workers and their guests and 24 hours security watch by expert security men (normally privately contracted) to prevent such criminal activities from happening at the site.

MITIGATION MEASURES

PROTECTION OF FLORA

In order to protect plant species from potential negative impacts, the proponent shall ensure that:

- The contractor is responsible for informing all employees about the need to prevent any harmful effects on natural vegetation on or around the construction site as a result of their activities;
- Clearing of natural vegetation is kept to a minimum;
- Unnecessary removal, damage and disturbance of natural vegetation are prohibited;
- Re-vegetation of the proposed project site is undertaken;
- Indigenous trees are planted around project area to enhance natural habitat

LAND DEGRADATION AND SOIL EROSION CONTROL

Potential negative impacts on land and soils shall be mitigated by ensuring that:

- The contractor implements erosion control measures as an on-going exercise;
- During construction, the contractor protects all areas susceptible to erosion by installing necessary temporary and permanent drainage works as soon as possible and by taking any other measures necessary to prevent storm water from concentrating in streams and scouring slopes, banks, etc.
- Any tunnels or erosion channels developed during the construction or maintenance period shall be backfilled and compacted and the areas restored to a proper condition;
- Areas where construction activities have been completed and where no further disturbance would take place are rehabilitated through re-vegetation;
- Ground clearance is minimized and if possible concentrated only to the specific building foundation areas, and only when it is necessary;
- Prompt reclamation of exposed soils is done;
- Construction during long rains period should be done with caution to avoid soil from being washed away;
- Topsoil excavated from buildings foundations is stored for re use on other areas like rehabilitations of quarries.

SOIL AND WATER POLLUTION MEASURES

Measures to mitigate soil and water pollution impacts during construction phase shall ensure that:

- Concrete mixing directly on the ground is prohibited and only be undertaken on impermeable surfaces;
- Concrete batching activities are located in an area of low environmental sensitivity;
- All runoff from batching areas is strictly controlled, cement-contaminated water is collected, stored and disposed of at an approved site;
- Contaminated water storage facilities are not left to overflow and appropriate protection from rain and flooding are implemented;
- Unused cement bags are stored out of the rain where runoff won't affect it;
- Used (empty) cement bags are; collected, stored in weatherproof containers to prevent windblown cement dust and water contamination, not to be used for any other purpose and shall be disposed of on a regular basis via the solid waste management system;
- All excess concrete is removed from site upon completion of concrete works and disposed of whilst preventing washing of the excess concrete into the ground;
- Entrance or accidental spillage, of solid matters, contaminants, debris and other pollutants and wastes into surface and ground water is prevented;
- Awareness of employees to prevent unnecessary oil spills and protection of environment in their daily duties is promoted; and
- All excess aggregate is removed from site and properly disposed.

WASTE MANAGEMENT

To ensure that solid waste is properly managed and potential negative impacts are mitigated, the contractor shall ensure that:

- All facilities are maintained in a neat and tidy condition. Measures to reduce the negligent behavior with regard to the disposal of all refuse are taken, bins, containers and refuse collection facilities for later disposal are provided at all places of work;

- Solid waste may be temporarily stored on site in a designated area prior to collection and disposal;
- Waste storage containers are covered, tip-proof, weatherproof and scavenger proof;
- No burning, on-site burying or dumping of waste shall occur;
- Inert construction rubble and waste materials are disposed of by burying in the borrow pits or a designated site;
- All excavated materials, debris from construction works are not to be stockpiled or deposited near or on-stream banks or other watercourse perimeter where they can be washed away by high water or storm runoff or can any way enter to water sources itself;
- Metal refuse bins or equivalent plastic refuse bins, all with lids, are provided to all buildings;
- Domestic refuse is collected and removed from all facilities at least twice per week and transported to the approved refuse disposal site in covered containers or trucks;
- Used oil, lubricants, cleaning materials, etc. from the maintenance of vehicles and machinery are collected in holding tanks and sent back to the supplier;
- Runoff from fuel depots / workshops / machinery washing areas and concrete batching areas is collected into a conservancy tank and disposed of designated site

AIR QUALITY CONTROL

The contractor shall ensure air quality by undertaking the following measures:

- Ensure that the generation of dust is minimized and implement a dust control program to maintain a safe working environment, minimize nuisance for surrounding residential areas/dwellings and protect damage to natural vegetation, crops, etc.;
- Exposed soil and material stockpiles shall be protected against wind erosion and the location of stockpiles shall take into consideration the prevailing wind directions and locations of sensitive receptors;
- To minimize the pollution caused by dust generation during the construction stage, water will be sprinkled on the construction site and on drive ways as frequently as possible;

- To minimize exhaust fumes, machinery and equipment shall not be running when not in use while ensuring that they regularly serviced; and
- Construction vehicles and machinery shall be equipped with pollution-control devices to minimize emissions

Vibration and Noise Control:

Vibration and noise produced by construction work will be managed as follows:

- The contractor shall strive to keep noise generating activities to a minimum;
- The contractor shall restrict all operations that result in undue noise disturbance to local communities and/or dwellings (e.g. drilling etc.) to daylight hours on weekdays;
- The contractor shall inform in advance any local communities and/or residents that could be disturbed by noise generating activities such as drilling or compacting and shall try to keep such activities to a minimum;
- The contractor shall be responsible for compliance with the relevant legislation with respect to noise;
- Provision of earplugs and earmuffs to the workers working in high peak noises during the construction stage;
- Use of modern low noise machinery and vehicles is recommended;
- Activities that may involve noises and vibration should be withheld at night especially close to human dwellings.

LANDSCAPE AND TOPOGRAPHY

As construction activities are very likely to lead to negative impact on landscape and topography at project site, such impacts will be brought to a minimum by executing the following measures:

- Planting of appropriate indigenous trees, grass cover and other vegetation types on project area should be encouraged so as to enhance scenic beauty of the area; and

- Removal and proper disposal of construction debris need to be affected after completion of construction works and shall not be stockpiled or deposited near or on water sources or other watercourse perimeter where they can be easily be washed away by high water or storm runoff or can any way enter these sources.

OCCUPATION HEALTH AND SAFETY MEASURES

The following safety measure should be observed during the construction stage:

- Provision of health and safety induction course to all workers;
- Instilling proper code of conduct and work ethics among construction workers and ensure that they are observed;
- Provision of Personal Protective Equipment (PPE) to all workers and enforce their use;
- Installing first aid kit and hire trained personnel to provide first aid;
- Reporting to OSHA within 24 hours of occurrence of any accident or near miss which can cause fatal or permanent disability; and
- Workers should be educated on their own safety and safety of others;
- For covid-19 prevention it is recommended:
- Workers are well-trained to practice and implement social distancing.
- No one is allowed to enter the premises of the project site without wearing proper mask.
- Personal hygiene practices are ensured and labor is trained for it by the contractor and the management of the unit.
- The proponent/contract provides masks to all the construction workers on daily basis and sanitizers are available at specific points of the project site.

IMPACT SIGNIFICANCE OF ECOLOGICAL IMPORTANCE

NATURAL VEGETATION

Project activities do not impose any potential impact on the area's natural vegetation and plantation.

ASSESSMENT OF IMPACT:

A significant impact will be interpreted if unnecessary or excessive removal and burning of plants for fuel wood is observed.

Nature of impact: Direct

Duration: long term

Timing: construction phase

Reversibility: irreversible

Likelihood: moderate

Consequences: Mild, as no rare plant species are not present in the project area.

Impact significance: significant

MITIGATION MEASURES:

The following mitigation measures will reduce any impact on vegetation:

- o Do not park vehicles on green belts/ grass
- o Unnecessary damage to vegetation will strictly be avoided.
- o Proponent will plant trees and other species after construction phase

RESIDUAL IMPACT:

Given the current state of the vegetation, and proper implementation of the proposed mitigation measures, slightly significant residual impact on the natural vegetation of the area is anticipated.

FAUNA

The fauna including wildlife species do not exist at the project site.

Nature of impact: Direct

Duration: short term



Timing: construction phase

Reversibility: not applicable

Likelihood: low

Consequences: Nil, as no rare plant species are not present in the areas.

Impact significance: not significant

RESIDUAL IMPACT:

Given the current state of the fauna there is no significant residual impact on the wild life of the area.

SOCIAL IMPORTANCE

Following parameters were adapted for the assessment of the well-being of the poor people near the project site that are used to assess the social, economic, and cultural impacts of the project.

MITIGATION MEASURES:

Efforts should also be made to discuss traffic conditions so that regular traffic is not disturbed. Transporters engaged for the project would be forced to adhere to the load specifications of the access road. No overloading would be allowed in any case.

Nature of impact: Direct

Duration: Short term

Timing: construction phase

Reversibility: reversible

Likelihood: low

Consequences: low, as it links the main Road and vehicles will rarely use the sub roads

Impact significance: slightly significant

CULTURAL ISSUES:

Induction of outside workers in the Contractor's labor may cause cultural issues with the local community as the local community is very sensitive about their cultural values. Also, theft problems to the local community may arise by the labor force and vice versa.

MITIGATION MEASURES:

Good relations with the local communities will be promoted by encouraging contractor to provide opportunities for skilled and unskilled employment to the locals, as well as on-the-job training in construction for young people. Project manager will restrict his staff to mix with the locals to avoid any social problem.

Contractor will keep the copies of Computerized National Identity Cards (CNIC) of his workers and will warn them not to involve in any theft activities. And if anyone would involve, he will have to pay heavy penalty. Similarly, at the time of employment contractor has to take care that the workers should be of good repute. The contractor camp will be properly fenced and main gate will be locked at night with a security guard to check the theft issues.

Contractor will also be the responsible for the sensitivity towards the local customs and traditions.

Nature of impact: Direct

Duration: Short term

Timing: construction phase

Reversibility: reversible

Likelihood: low

Consequences: low, if project proponent implements mitigation measure, its impact will be low

Impact significance: slightly significant

ACCIDENT RISKS:

Unmonitored construction activities may create an accident risk for the local residents particularly children and labor force.

MITIGATION MEASURES:

Contractor must have first aid kits along with the medical officer in the field if a minor injury takes place, but for an unfortunate accident service of nearby hospitals will be availed. Routine medical check-ups of all the field staff including unskilled labor need to be conducted by a qualified doctor.

Training of the workers should be arranged regarding safety procedures, environmental awareness, equipping all construction workers with PPEs, safety boots, safety helmets, ear plugs, gloves and protective masks. Monitoring must be carried out to check for the sustainable use of PPEs.

Nature of impact: Direct

Duration: Short term

Reversibility: not applicable

Likelihood: moderate

Consequences: moderate, as complete trainings and mitigation measure have been planned.

Impact significance: significant

PRIVACY ISSUES:

Disturbance may happen to the privacy of women residing in the work area when workers will work at height.

MITIGATION MEASURES:

Contractor must take care for the privacy of residents, especially women near the working area.

Nature of impact: Direct

Duration: Short term

Reversibility: reversible

Likelihood: low

Consequences: low, as contractor will take care of the matter

Impact significance: slightly significant

SHARING OF RESOURCES:

During the operational phase of the project, workers will share the common resources like potable water, fuel, wood. It may create conflicts between work force and local population.

MITIGATION MEASURES:

The contractor will be required to maintain a close friendly relationship with the local communities to ensure that there may not be any conflict related to common resources utilization. He must get permission of the local population before using their common sources of water and other resources.

Nature of impact: Direct

Duration: Short term

Timing: construction phase

Reversibility: reversible

Likelihood: low

Consequences: low, if the terms & conditions will be followed and mitigation measures have been employed

Impact significance: significant

NOISE PROBLEMS:

Residents of the area and neighbors may face the problems of noise during the construction and operations phase.

MITIGATION MEASURES:

Large noise generating activities should be carried out in fixed hours. The timing will be known to all the people in 500 m radius of the site.

Nature of impact: Direct

Duration: Short term

Reversibility: reversible

Likelihood: Moderate

Consequences: Moderate, project contractor will follow the safety guidelines & NEQS

Impact significance: significant

MOBILIZATION ISSUES:

During the construction phase, the general mobility of the local residents and their livestock in and around the study area is likely to be hindered.

MITIGATION MEASURES:

It will be the responsibility of project contractor and drivers to follow the speed limits in the area.

Nature of impact: Direct

Duration: Short term

Timing: construction phase

Reversibility: reversible

Likelihood: low

Consequences: low, as it links the main Rawat industrial estate Road and vehicles will rarely use the sub roads

Impact significance: slightly significant

ENVIRONMENTAL STANDARDS

TOPOGRAPHY:

The project will not change the topography of the area as proponent committed to sustainable development of project. The infrastructure of the area will be maintained after the construction activities.

RESIDUAL IMPACT:

The residual impact of project activities on the topography of the area is expected to be insignificant.

The residual effects are summarized below:

Nature of impact: direct

Timing: construction Phase

Likelihood: Nil

Consequences: no change

Impact significance: Not significant

LAND ACQUISITION RESETTLEMENT:

One of the major impacts includes acquisition of land from the land owners and the resulting displacement of their families and disturbances in the livelihood of the affected persons (AP) in the project area. But present project is present in industrial area and is the property of M/s Crystolite Pharmaceuticals and do not involve any type of land acquisition and resettlement activity.

RESIDUAL IMPACT:

After implementing the mitigation measures listed above, the residual impact of the solid waste/ sludge is expected to be insignificant.

ENVIRONMENTAL IMPACTS DURING OPERATION STAGE

AIR QUALITY POTENTIAL IMPACT:

Air emissions from project-related activities are likely to include:

- o Dust raised on dirt tracks by project-related vehicles.
- o Combustion products (nitrogen oxides, sulfur dioxide, particulate matter, carbon monoxide, and volatile organic compounds) from vehicles used for project-related activities.

ASSESSMENT OF IMPACT

1) DUST EMISSIONS:

Dust emissions caused by vehicular traffic on dirt track are an important concern, primarily when such traffic passes near community settlements. Dust emissions cause the amount of particulate matter in the air to increase, and thus become a health concern. Dust clouds also reduce road visibility, creating a traffic hazard.

2) GASEOUS EMISSIONS:

Emissions produced by vehicles and equipment will be similar to those produced by generators in terms of the resulting pollutants (SO₂, NO_x, PM, etc.). However, the extent to

which they are produced will be kept considerably lower, since much smaller engines are used in vehicles and construction machinery.

Nature of impact: Direct

Duration: long term

Timing: operation/ construction

Reversibility: irreversible

Likelihood: moderate as mitigation measures will ensure that air pollution remains within acceptable limits.

Consequences: moderate, as pollutant levels in the ambient air will be well within acceptable limits.

Impact significance: moderate, based upon low likelihood and mild to moderate consequence.

MITIGATION MEASURES

None of the potential effects discussed above are expected to exceed acceptable limits.

The mitigation measures given below will further reduce their impact, and ensure that they remain within acceptable limits.

- o All equipment and vehicles used during the project will be properly tuned and maintained in good working condition in order to minimize exhaust emissions.
- o Vehicle speed will be reduced on track passing through or close to shops
- o Imposing speed limits and encouraging more efficient journey management will reduce the dust emissions produced by vehicular traffic. Water will be sprinkled where necessary to contain dust emissions.
- o Management will make sure process is environmentally friendly.

RESIDUAL IMPACT:

After implementing the mitigation measures listed above, the residual impact of the proposed activities on ambient air quality is expected to be low.

NOISE LEVEL:

Noise may be a major concern during the operation phase. It can be generated from the machinery used during operational activities. Generators can be another source of noise pollution.

Nature of impact: Direct

Duration: long term

Timing: operation/ construction

Reversibility: Not applicable

Likelihood: moderate

Consequences: slightly significant, if above mentioned mitigation measure will be strictly followed

Impact significance: moderate, based upon low likelihood and mild to moderate consequence.

MITIGATION MEASURES:

- o Keep the traffic load aligned and minimum during working hours of project
- o Machinery and vehicles must be well tuned and maintained
- o Impose the limits on unnecessary use of horns
- o Safety signs must be displayed and public & drivers must be well aware of them
- o Do not work in night time.

RESIDUAL IMPACT:

After implementing the mitigation measures listed above, the residual impact of the noise level will be slightly significant.

CONCLUSION

Management of M/s Crystolite Pharmaceuticals has to achieve the following goals.

- o Identification of regulatory requirements that apply to the project activities in the context of environmental protection.
- o Identification of the environmental features of the project area and the likely impact of the project on the environment,

- o Recommendation of appropriate mitigation measures that management will incorporate into the project implementation to minimize all adverse environmental impacts.
- o Baseline environmental and socioeconomic information collection from a variety of sources, including field surveys.

The impacts of project in area will be insignificant, provided the generic mitigation measures proposed in this report are implemented.

After assessing the project activities and investigating the project area, it is concluded that, if the activities are undertaken in this report, and the recommended mitigation and environmental management measures are adopted, the project will not result in any long-term or significant impacts on the local community or the environment.

HEALTH:

People from the project area regularly travel to other cities, and thus cannot be considered isolated from the rest of the country. They are regularly exposed to illnesses common to urban populations, and have similar levels of immunity. The project is therefore very unlikely to lead to an epidemic of any sort among local communities.

MITIGATION MEASURES:

Regular medical check-ups of all the workers need to be conducted to ensure the health of workers and local population.

Nature of impact: Indirect

Duration: Long term

Timing: operation phase

Reversibility: reversible

Likelihood: moderate

Consequences: low to moderate, it may cause disturbance or spread of disease in the area if mitigation measure will not have followed

Impact significance: significant

SAFETY:

Project activities could become a hazard as it is located in populated area local people, especially children, are likely to gather around to watch the activity. The other safety issue is that of traffic, especially along access roads close to settlements. To reduce the hazards, the following mitigation measures will be implemented:

- o Local people will be informed in advance when work is about to start in an area.
- o This may result in people keeping young children away from work areas.
- o Machinery will never be left unattended.
- o Safe driving practices will be adopted, particularly while passing through settlements.

Nature of impact: Direct

Duration: long term

Timing: construction / operation phase

Reversibility: irreversible

Likelihood: moderate to high

Consequences: moderate if all safety measure will be taken care

Impact significance: Significant

SOLID WASTE/ SLUDGE MANAGEMENT:

Proper solid waste management system is necessary for the prompt, timely and efficient disposal of solid waste & sludge for the reduction of its impacts. Impacts due to solid waste & sludge are expected to be temporary and minor in nature.

Nature of impact: Direct

Duration: Short term

Timing: operation

Reversibility: Not applicable

Likelihood: Low (unlikely) as mitigation measures will ensure that Solid waste management will be efficient

Consequences: Mild, as it will be removed from site within few hours

Impact significance: Low, based upon low likelihood and mild to moderate consequence.

MITIGATION MEASURES:

- o Planning of solid waste disposal sites with reasonable distance from the human settlements
- o A minimum distance of 1 km should be maintained between the solid waste disposal site and nearest human settlement
- o Devise plan & develop guidelines for the safe handling, storage & disposal
- o Sludge must not be placed at the site after cleaning of wastewater treatment tank
- o PPEs are strongly recommended for workers for the handling of sludge.

POTENTIAL POSITIVE IMPACTS:

The project is envisaged to have followed major positive impacts;

EMPLOYMENT OPPORTUNITIES:

Establishment of M/s Crytolite Pharmaceuticals will help in generating new jobs for the local population. The requirement of Managers, Engineers, Workers, technicians, skilled and unskilled labor etc. will generate employment opportunities. It is estimated about 20-25 persons will be employed during operational phase. Hence, there is large number of employment opportunities especially for the locals of the district.

INCREASE IN BUSINESS:

With the influx of laborers for the proposed project, there will be more opportunities for small scale business such as small food cafes etc.

IMPROVED INFRASTRUCTURE:

Establishment of M/s Crytolite Pharmaceuticals will improve the infrastructure of the area as proponent has incorporated aesthetic values and regeneration of site in its planning stage.

ECONOMIC BENEFITS:

M/s Crytolite Pharmaceuticals is a medicinal formulation unit and it will be a great investment for the economy of our country. In the long run it will positively impact not only the local population but also the economy of Pakistan.

Main environmental issues associated with Project operation are as follows.

- Health and safety issues for workers may arise during the project process e.g., Particulate matter may be generated during the project process, which may cause the health issues for the workers and noise of machinery can also be a negative impact on the health of workers.
- Waste water due to domestic and process activities.
- Fire due to short circuits and other activities.
- Solid waste generation due to domestic and project related activities.
- Noise pollution from generator and other machinery.
- Health hazards including the electricity hazards.
- Emissions will be generated from working of generators.
- Sludge from wastewater treatment facility will be generated.
- Vehicle access is required especially for transportation. The site is well served with the road network. Heavy traffic will be allowed only during tight time during operational phase. The traffic issues at any stage of project life cycle will not arise.

Impact significance: moderate to high or may be negative

Nature of impact: direct

Duration: Long-term

Timing: operational phase

Reversibility: NA

Likelihood: moderate to high

Consequences: moderate to high or may be negative

RECOMMENDATIONS

- Safety of workers should be ensured through proper training and PPEs must be ensured during the working hours.
- Wastewater treatment facility should be constructed within the premises of the unit.
- A well design firefighting system will be constructed to cope with fire situations in the subject project.
- Solid waste bins should be regularly cleaned and solid waste must be handed over to contractor.
- Sludge from the wastewater treatment facility will be handed over to the certified contractors.
- Noise levels should not exceed the PEQS.

POTENTIAL ENVIRONMENTAL ENHANCEMENT MEASURES

The project will be installed with all precautionary measures to enhance and safe the environment. Following necessary measures will be adopted during construction and operation:

- Sprinkling of water will be done on dusty roads and tracks.
- PPEs will be provided during construction activity.
- Local people will be informed in advance when work is about to start in an area.
- Machinery will never be left unattended.
- Efforts should also be made to discuss traffic conditions so that regular traffic is not disturbed. Transporters engaged for the project would be forced to adhere to the load specifications of the access road. No overloading would be allowed in any case.
- Machinery will be kept maintained.
- Waste water will be treated through waste treatment system that will be installed within the premises of the subject project.
- Area will be restored with native plants. A proper tree plantation plan will be formulated to save the environment.
- It is recommended that Solid waste should be handed over to contractors and agreement should be made.
- Noise will be controlled by adopting proper measures.
- PPEs will be provided to workers during working.
- Firefighting equipment's and system will be installed.
- Safety signs will be placed at all locations where required.
- Hygienic conditions will be ensured and proper quality will be maintained by quality control testing.
- First aid facilities will be made available.

PURPOSE OF MITIGATION MEASURES

WHAT IS THE PROBLEM I.E. IN TERMS OF “MAJOR ENVIRONMENTAL IMPACTS” WHICH MAY ARISE BY THE SUBJECT PROJECT ACTIVITY?

The major impacts may arise by the subject project could be particulate matter & dust, noise, solid waste and wastewater. Other impacts are of minor importance. These impacts will arise

during operation but precautionary measures will be adopted prior to start the activity, during the activity and post activity.

WHEN THE PROBLEM WILL OCCUR AND WHEN IT SHOULD BE ADDRESSED?

Any impact that would arise due to the subject project activity will be addressed on site. Trainings will be conducted on site prior to start work while other precautionary measures will also be adopted to make the project safe and environmentally friendly.

WHERE AND HOW THE PROBLEM SHOULD BE ADDRESSED?

HSE manager/environmental manager along with site manager will be appointed to assess any impact that could be arisen during both phases. He would be responsible to address the problem and to mitigate it.

WHYS OF ACHIEVING MITIGATION MEASURES

IMPROVED MONITORING AND MANAGEMENT PRACTICES:

Management of M/s Crystolite Pharmaceuticals shall take appropriate measures to provide pollution free and safe environment during the project activity by implementing improved management practices and monitoring techniques suggested in EMP.

COMPENSATION IN MONEY TERMS:

M/s Crystolite Pharmaceuticals will adopt such plan that will assure the minimum impact on the environment and health by implementing proper mitigation measures.

REPLACEMENT, RELOCATION AND REHABILITATION:

M/s Crystolite Pharmaceuticals will develop Restoration/ reclamation or tree plantation plan to restore the project area. Maximum Plantation will be done with native species within the building, along the boundary wall and along the road side if directed by EPA. Also, in-front of main area, horticulture plan will be formulated and area for this will be kept reserved.

CHAPTER # 6

ENVIRONMENTAL MANAGEMENT AND MONITORING PROGRAM

PURPOSE AND OBJECTIVES OF THE EMP:

The primary objectives of the EMP are to:

- Facilitate the implementation of the mitigation measures identified in the EIA.
- Define the responsibilities of the project proponent.
- Define a monitoring mechanism and identify monitoring parameters in order to:
 1. Ensure the complete implementation of all mitigation measures.
 2. Ensure the effectiveness of the mitigation measures.
 3. Provide a mechanism for taking timely action in the face of unanticipated environmental situations.
 4. Identify training requirements at various levels.

MANAGEMENT APPROACH:

The overall responsibility for compliance with the environmental management plan rests with the project proponent.

A certain degree of redundancy is inevitable across all management levels, but this is in order to ensure that compliance with the environmental management plan is crosschecked.

INSTITUTIONAL CAPACITY

Following functionaries will be involved in the implementation of EMP:

- Project Proponent
- HSE/Project Manager
- In-Charge Administration
- Supervisor of project

SCHEDULE OF IMPLEMENTATION

Training for the management and workers on environmental aspects of the project will be arranged on biannually basis during the operational phase of the project. It will be imparted by a team of experienced trainers.



Figure: Institutional Capacity for the implementation of EMP

Management will hire or appoint HSE officer before the initiation of work at the project site. HSE officer will be responsible for conducting the training of the labor, which will be organized either by the management of industry or by the contractor.

Following schedules of training will be implemented:

Table: Training Program

Sr. No.	Description of program	Personnel involved	Time/ duration
1)	General HSE Training	Trainers and whole production facility staff	Regularly as planned by HSE Manager
2)	Instrument use/ workplace specific items	Trainers and whole production facility	Regularly as planned by HSE Manager

		staff	
3)	PPEs use and safe work practices at work site.	Trainers and whole production facility staff	Regularly as planned by HSE Manager
4)	Reporting and investigating accidents/ incidents	Trainers and whole production facility staff	Regularly as planned by HSE Manager
5)	Emergency procedures	Trainers and whole production facility staff	Regularly as planned by HSE Manager
6)	Medical and first aid	Trainers and whole production facility staff	Regularly as planned by HSE Manager
7)	Health and safety promotion	Trainers and whole production facility staff	Regularly as planned by HSE Manager

In order to raise the level of professional and managerial staff, there is a need to upgrade their knowledge in the related areas. HSE Manager should play a key role in this respect and arrange the training programs. HSE Manager will provide training to staff and workers about the best environmental management practices at the site and affective implementation of the EMMP. The training modules will include air, noise and water pollution monitoring, social awareness, Environmental Laws, National Environmental Quality Standards (PEQS), Usage of personal protection equipment, and health and safety related issues on the construction site.

The HSE Manager will train all workers & staff in basic sanitation and health care issues (e.g., how to avoid malaria, dengue and transmission of Sexually Transmitted Infections (STI) HIV/AIDS and in general health and safety matters, and on the specific hazards of their

work. Training should also consist of basic hazard awareness, site specific hazards, safe work practices, and emergency procedures for fire, evacuation.

HSE Manager will be responsible to conduct Training on regularly basis regarding health & safety, hygiene, firefighting and first aid.

TRAINING OF BUILDING CONTRACTOR

Training of building contractor & workers will be the part of the TORs regarding the construction of the scheme. The provisions given in EIA Report Chapter 4 Screening of Potential Environmental Impacts & Their Mitigation Measures will be followed.

TORs will be including the training and submission of reports in the following area:

1. Handling of Machineries in a safe way
2. Use of PPEs
3. Maintenance of vehicles and submission of Environmental Monitoring Reports
4. Maintenance of Water Consumption records
5. Testing of water and waste water and submission of Environmental Monitoring Reports
6. Placement of safety signs/boards during construction
7. Sprinkling of water on the roads and dusty tracks
8. Monitoring of generator emissions

Training regarding all other aspects of HSE will be ensured by the contractor during the construction phase.

PROPOSED ENVIRONMENTAL MONITORING

To oversee the environmental performance of the project through its lifecycle enforcing the PEQS an Environmental Monitoring Program should be formulated which ensures effective surveillance of the environmental parameters at various stages of the project development and compliances with PEQS and legal obligations. Monitoring for following Environmental Parameters is recommended:

- **AMBIENT AIR**

Monitoring for ambient air should be conducted during operational activities of the project and report should be submitted to EPA Punjab.

- **NOISE**



Regular monitoring for noise level should be maintained periodically during operation phases of the project and report should be submitted to EPA Punjab as per rule.

- **WATER QUALITY**

Regular monitoring of water quality should be conducted during operational phases of the project and report should be submitted to EPA Punjab. Record should be maintained regarding the underground water pump and consumption.

Recommendation: Environmental Monitoring data log book should be maintained by the project proponent.

RESPONSIBILITY OF EMP

Overall responsibility for implementation of EMP is of project proponent. He has appointed an HSE/Project Manager of relevant qualification. HSE/Project Manager acts as Environmental Manager and will manage all HSE condition at the PEQS.

EQUIPMENT MAINTENANCE DETAIL

The subject project is the establishment of medicinal formulation unit under the name of M/s Crytolite Pharmaceuticals. The company will maintain the records for Health Safety & Environment and will hire HSE manager to check and deal with the HSE issues. The company shall maintain PPEs, medical facilities, firefighting Equipment's as fire buckets, fire hydrants and fire extinguishers and records for their periodic filings or replacement. Sops for emergency preparedness and response is attached as **Annexure-L** and sops and list of fire extinguishers are attached as **Annexure-M**.

ENVIRONMENTAL BUDGET

The cost which is required to effectively implement the mitigation measures is important for the sustainability of the Project in operation stage of the Project.

Company has allocated the Environmental Budget annually for the Training, maintenance and management of Environment that will include filling and maintenance of equipment's, restoration, plantation, and availability of PPEs, strategic planning to cope with any emergency situation and formulate the disaster management plan to cope with natural disaster. Any equipment or devices failure or replacement will not be included in this budget.

HSE training	On regular basis

Maintenance and management of environment	On regular basis
Maintenance of equipment	On regular basis
Availability of PPEs	During production hours
Strategic planning to cope with any emergency	As per policy
Formulate the disaster management plan to cope with natural disaster	As per policy

ENVIRONMENTAL MANAGEMENT PLAN OF M/s CRYSTOLITE PHARMACEUTICALS

Sr. #	Aspects	Impact & Mitigations to be taken			
		Impacts	Mitigation measures Construction/Operation	Responsibility	Monitoring
AMBIENT AIR QUALITY					
1.	Air Quality	Production machinery Flue gas emissions from machinery and generators	Air emissions-controlled devices must be installed to control the air pollution. For generators, small scrubbers should be installed. Air quality monitoring is recommended on regular base Open disposal and burning of solid waste in the premises of building should be strictly banned. Pollution abatement technologies regarding air pollution will be adopted. Emissions inspection and monitoring should be done on regular basis	HSE Department	Environmental Consultant/EPA PUNJAB

NOISE & VIBRATION					
2.	Noise	The major sources of the noise are production related machinery. Noise from generators (if any)	Personal Protective Equipment PPEs including Ear muffs, Ear plugs and other noise abating equipment will be provided to the workers and other staff. Sound proof room should be built for generator (if any) to control the noise.	HSE department	Environmental Consultant/ EPA PUNJAB
HEALTH AND SAFETY					
3.	Health and safety	Health & safety issues of workers and nearby community	Trainings of the workers is recommended for health & safety, first aid and firefighting. Sops and list for fire extinguishers is attached as Annexure-M . Proponent must provide First aid facilities to workers in case of any injury or accident. Safe drinking water must be provided to workers, staff, and poor people of the area. Water consumption records should be maintained. Provision of Proper PPEs must be ensured at workplace. Assembly point and exit points must be available at workplace. Electric wires, D. Bs must be kept covered & closed	HSE Department	Environmental Consultant/ EPA

			to avoid any electric hazards. Smoking or any drugs should be prohibited during working hours or performing work. Safety signs & boards will be placed at the time of construction activity. Security guards will be appointed at the construction site. Sops for emergency response preparedness and response are attached as Annexure-L.		
WASTE WATER					
4.	Waste water	Domestic waste water. Minor wastewater from production activities. Spread of diseases, underground water contamination.	Domestic waste water is being drained out in industrial estate drain after treated in septic tanks An appropriately designed septic tank is being used to treat sewage/waste water to achieve PEQS. Periodic cleaning of septic tank is recommended.	HSE department	Environmental Consultant
SOLID WASTE GENERATION					
5.	Solid Waste Generation	Aesthetic degradation, foul smell etc. Solid waste generation from the machinery installation and	A solid waste management plan should be formulated to deal with the proper disposal of solid waste, supervised by HSE Manager. Waste segregation is recommended at the source.	HSE Department	Environmental Consultant/ EPA PUNJAB

		production activities, domestic and process sources	Industrial ecology practices will be adopted wherever possible. 7 R's of sustainability is recommended Hazardous waste should be disposed in separate bins and handed over to EPA approved contractors. Waste produced from building alteration/renovation should be sold to local market.		
ODOR					
6.	Odor	Odor may produce from raw material and during product manufacturing	Raw material should be covered to reduce odor Face masks must be provided to the workers and employees on production floor	HSE Department	Environmental Consultant/ EPA PUNJAB
ENERGY REQUIREMENT					
7.	Energy requirement	Resource depletion	Do not waste the energy/electricity when there is no need of it. Use energy efficient and ecofriendly equipment Use energy saving appliances Conduct and maintain records for energy audits Do not leave the appliances in running when there is no need It is recommended to save and conserve the energy and adopt energy efficient technologies in the factory.	HSE Department	Environmental Consultant/ EPA PUNJAB

SOCIO ECONOMIC IMPACTS					
8.	Language	Change in cultural language	Maximum employment of Local people is recommended to preserve the local cultural language. It will help in communication with the local people to resolve any emerging issue near the project area	Proponent	NA
9.	Education	Change in social behavior and economic gains	School and colleges exist in the area. The project proponent will initiate an educational awareness program with the coordination of the local people.	Proponent	NGO survey
10	Health	Social performance of the individuals in the area	The project proponent will assist the local impacted community for the improvement of health services Health clinic must be established for the project workers.	Proponent	Proponent
11	Culture and norms of the area	Change in culture by the influx of nomadic people	Maximum local employment should be ensured to preserve the culture of the area	Proponent	NGO survey/Environmental Consultant
12	Sewage and waste disposal	Diseases caused by improper sanitation	Subject project will uplift the economic status of the nearest human settlements. Awareness program will be initiated regarding the disposal of waste.	Proponent/ local NGO	NGO survey/ Environmental Consultant

CHAPTER # 7

STAKEHOLDERS PARTICIPATION

Social acceptability of the project and the area is a key to success. Consultation with the stakeholders is a tool for managing two-way communication between the project proponent and the affected public. Its goal is to improve decision making and built understanding by actively involving individuals, groups and organizations, which have stake in the project. This involvement increases project's long-term viability and enhances its benefits to locally affected people and other stakeholders.

In order to evaluate the socioeconomic and environmental impacts, filed surveys are extremely essential. In addition to the surveys at the preliminary stage, consultation with the community and their active participation plays a vital role in successful implementation of the project. To identity the different types of stakeholders and ascertain their perceptions about the project, an initial environmental examination was conducted. Informal group discussions were also held as an additional tool for obtaining feedback from the stakeholders that are being discussed in the following pages.

OBJECTIVES OF CONSULTATION

Public consultation plays a vital role in studying the effects of the project on the stakeholders and in the successful implementation and execution of the proposed project. Public involvement is a compulsory feature of environmental assessment, which leads to better and more acceptable decision making. The objective of the consultation with stakeholders is to help verify the environmental and social issues that have been presumed to arise and to identify those which are not known or are unique to the construction of the proposed unit.

The important general objectives of the consultation process are:

- Information dissemination, education and liaison;
- Identification of problems and needs;
- Collaborative problem solving;
- Reaction, comment and feedback on proposed project;
- Documenting mitigation measures proposed by the stakeholders;

METHODOLOGY OF CONSULTATION:

The EIA team carried out public consultations at various locations around the Project Site. The stakeholder's consultation during this phase of the work targeted the project area, administrative and private offices, Govt. offices, shops, etc. near the Project area:

- Selection of the stakeholders for consultation, reconnaissance of the project site and initial discussions with the neighboring industry workers, villagers, shopkeepers, drivers etc.
- Environmental consultants and social specialists and documenting the opinions of the stakeholders expressed during the meetings etc.

PROPONENT

Possible impacts and mitigation measures related to the subject project were discussed with the project proponent and management. They assured to take all suggested mitigation measures to control any discrepancy arose by the project and to make the project environment friendly.

RESPONSIBLE AUTHORITY

Management of M/s Crystolite Pharmaceuticals is the responsible authority to take all measures prior to start the activity.

ENVIRONMENTAL PRACTITIONERS AND EXPERTS

Team of M/s Pak Green Enviro-Engineering Pvt. Ltd visited the project site, had discussions with stakeholders and consulted with the local people of nearby and other villages to evaluate the project socio-economic impacts. People provide the massive information about the project and have positive remarks regarding the project development.

OTHER DEPARTMENTS AND AGENCIES

For the impact analysis detailed meetings were held with the management of M/s Crystolite Pharmaceuticals, local community, education institutes, health institutes and hospitals. Issues were discussed that may affect the environment and also the implementation of proposed project. All possible mitigation measures were considered and incorporated in the Environmental Management Plan.

Scoping sessions, focused group discussion and way side consultations were held with the relevant stakeholders in the area. The purpose of such consultations is to obtain the feedback from the relevant persons.

AFFECTED & WIDER COMMUNITY

There is no affected community present in the radius of our study area. PGEE team has consulted with the inhabitants of the different villages. They provided positive remarks regarding the subject project and in the favor of the subject activity for the proposed plant. Stakeholder's participation Performa's and socioeconomic questionnaire were get filled by the inhabitants to evaluate the project socio-economic impacts. List of respondents and socioeconomic questionnaires are attached as **Annexure-O** with the report.

Categories of stakeholders interviewed in the project area:

Sr. No.	Stakeholder Category
1.	Neighboring factory workers.
2.	Nearby residents
3.	Shopkeepers.
4.	Drivers.

In addition to the above categories, authorities of administrative and educational institutions, commerce and Investment Department (C&I), Environmental Protection Department (EPD) etc. were also consulted for more effective participation and appraisal of the proposed project.

ISSUES DISCUSSED:

Following issues were discussed during the stakeholder consultation:

- Overall activities of the project;
- Possible impacts on natural vegetation, air, land and properties;
- Possible mitigation measures;

- Benefits of the project specifically for the local people.

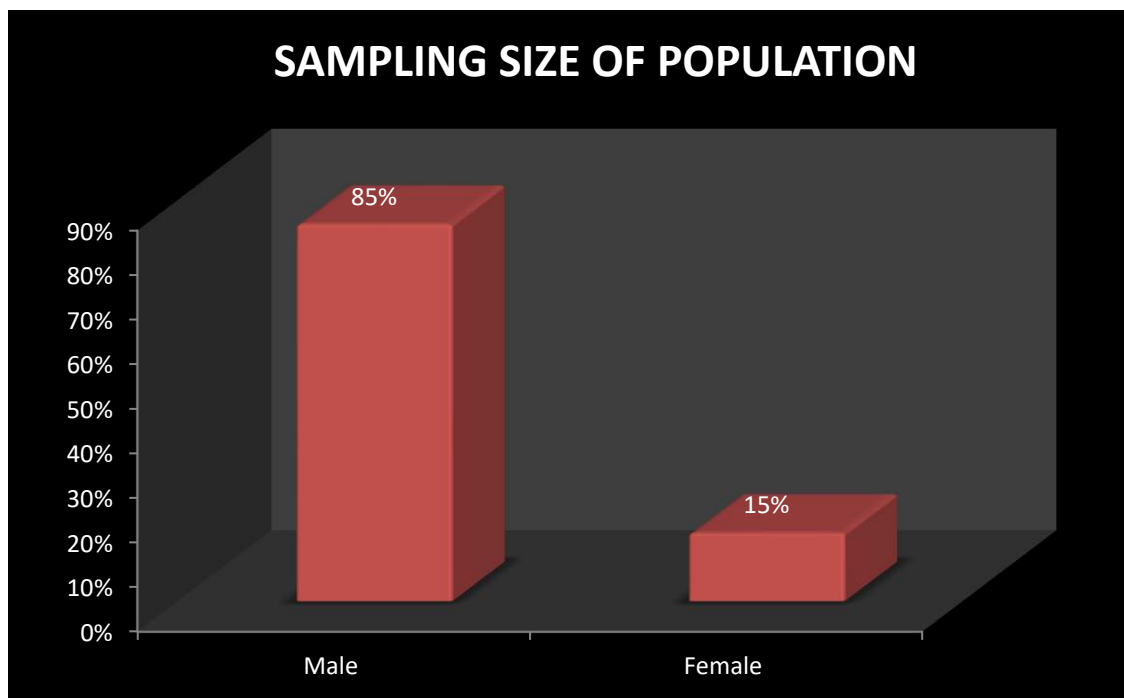
SAMPLE SIZE

Sample size of 30 respondents was selected by the Team of consultants for conducting the socioeconomic survey. Women were also consulted for the said survey; some of their names are mentioned in the above list of respondents while most of them were not willing to give personal information.

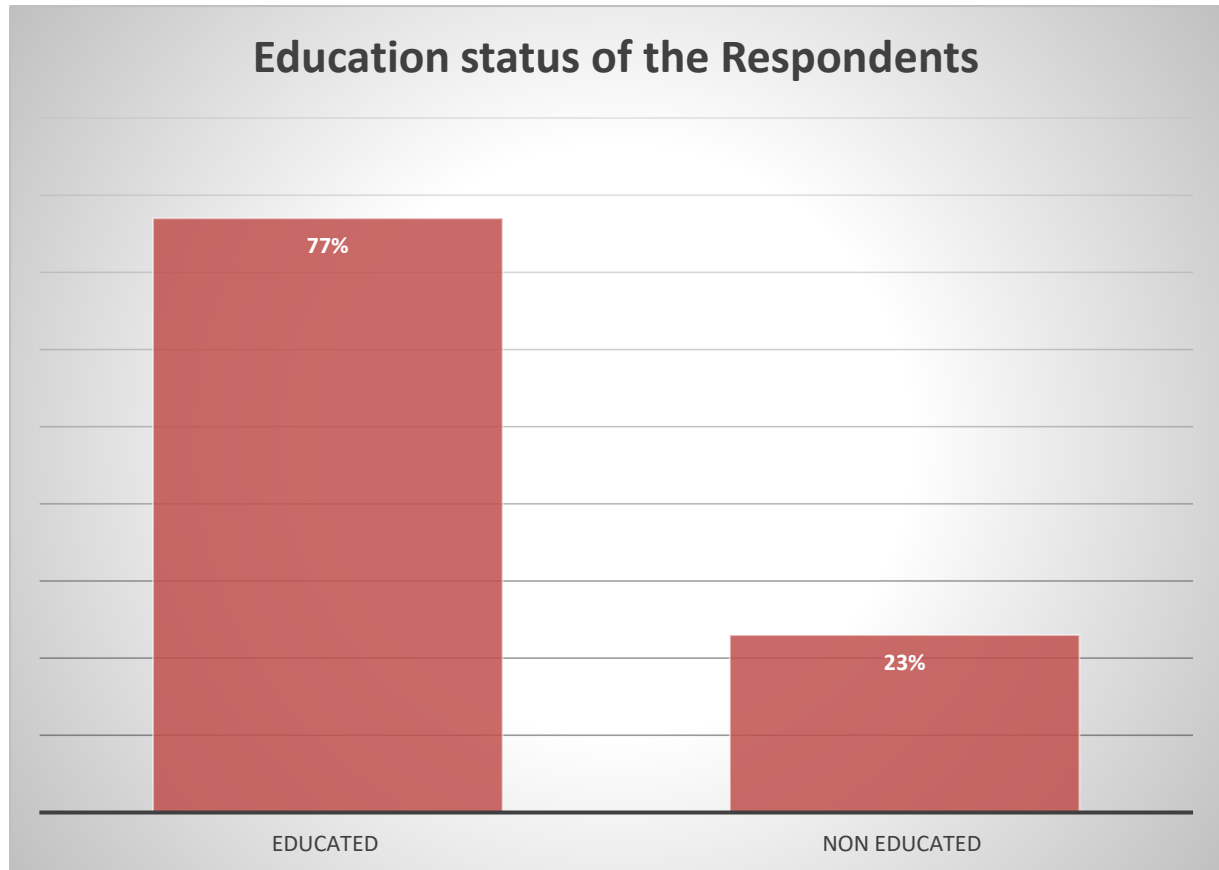
STATISTICAL ANALYSIS

SPSS 19.0 has been used for the statistical analysis of the data collected during the visit of study site area through questionnaires, List of questionnaires is attached herewith.

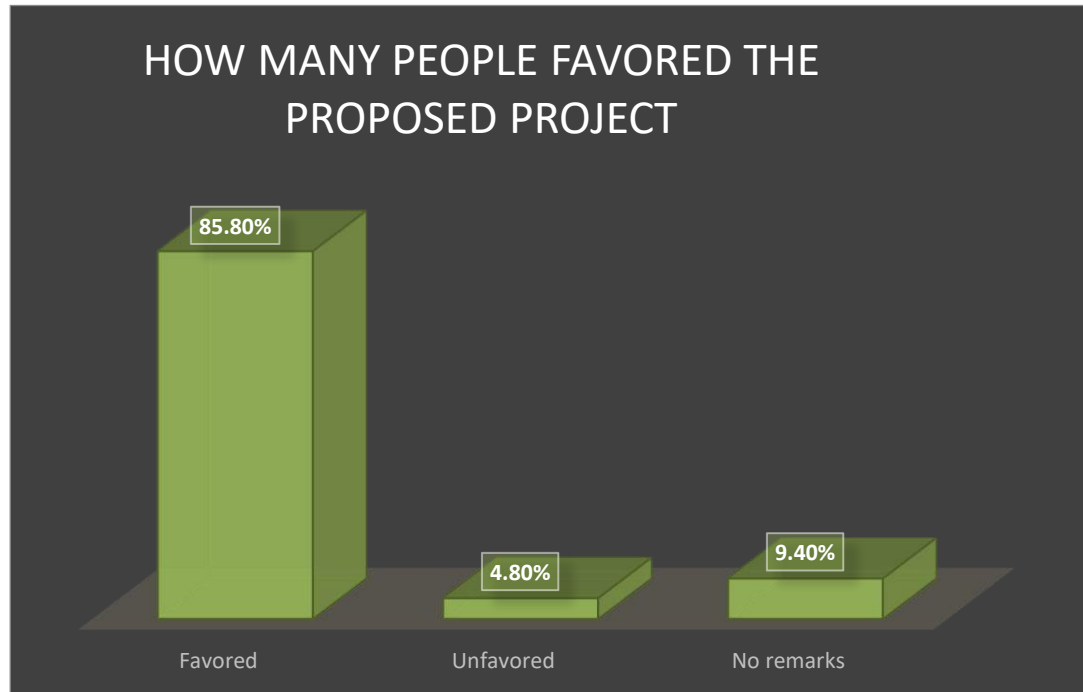
Graphical representation of analysis is given below:



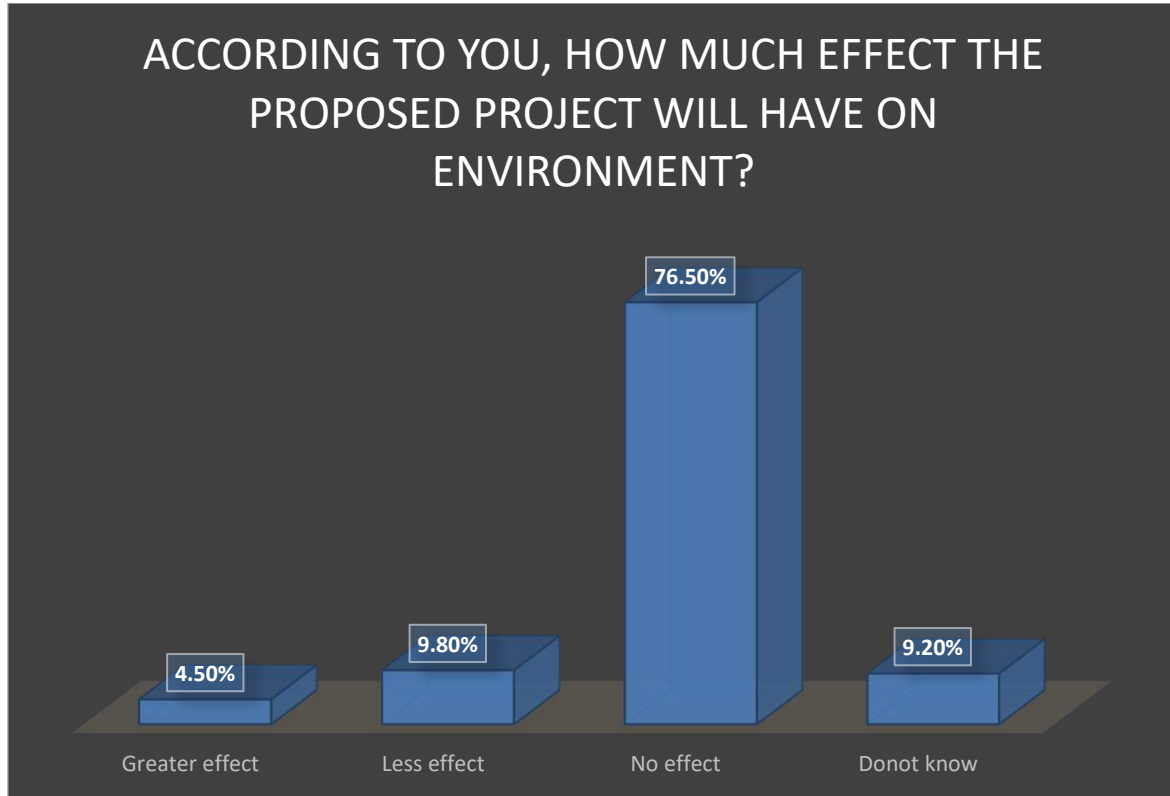
In the sampled population, 85% respondents were male while 15% respondents were female. The number of female respondents is less as compared to male respondents because according to the social binding female hesitates to respond or communicate comfortably.



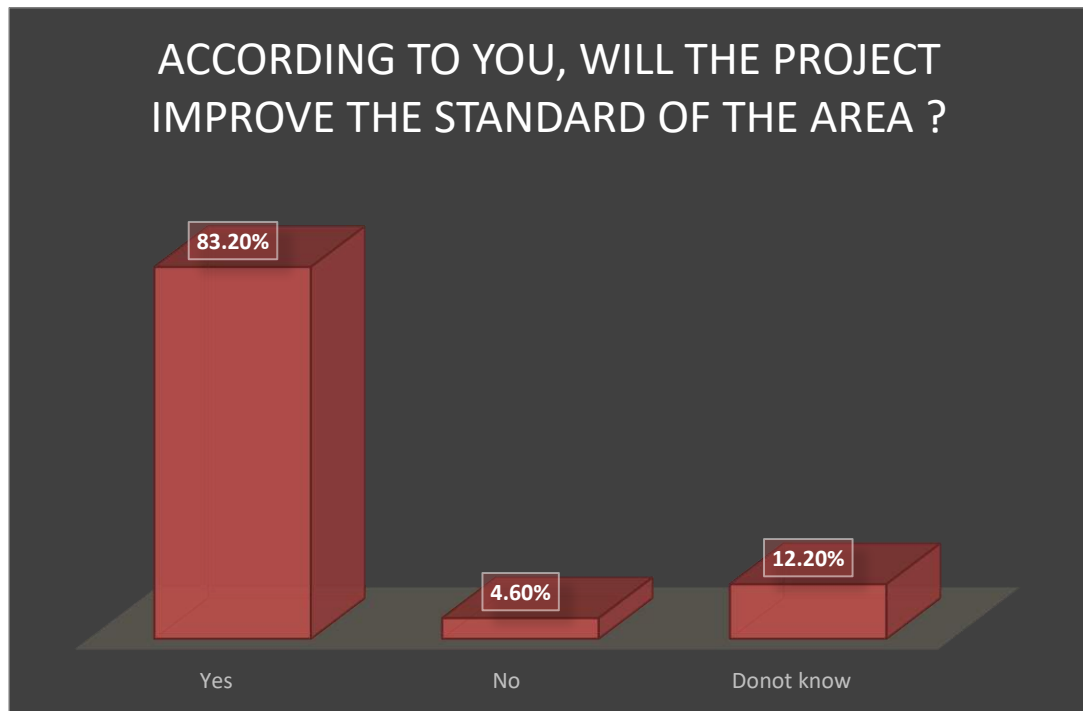
In the sampled population, 77% respondents were educated while 23% were uneducated. Overall education status of the area is good.



As per survey, 85.80 % people favored the project and they gave positive remarks regarding the subject project. While 9.40% respondents had no opinion regarding the project and 4.80% respondents were not satisfied with the project because they think that development will affect the natural aesthetics of the area.



As per survey, 4.50% respondents said that subject project will affect the environment of the area, 9.8% said that there will be less effect on the environment, 76.50% respondents said that the project will not affect the environment and 9.20% said that they have no idea regarding the subject project. Most of the population was not aware about the environmental importance; they were giving their remarks according to their own knowledge



As Per survey, 83.2 % people said that the project will improve the standard of the area, 4.60% said that it will have no impact on the area while 12.20 % respondents gave no remarks.

FINDINGS OF THE OVERALL DISCUSSION:

- + It will enhance the socio-economic conditions/values of the area.
- + Project will increase revenue generation for the Government.
- + It will create employment opportunities.
- + Local people will be given preference for employment in the proposed project.
- + Construction of the project will be completed in the designated timeframe to limit adverse impacts of construction.
- + There will be no significant additional load on the existing infrastructure i.e. utilities of water, telephone, electricity etc. due to the development of the proposed project.

CHAPTER # 8

CONCLUSION AND RECOMMENDATIONS

Based on the study conducted for Environment Impact Assessment (EIA) for the subject project, the following conclusions are made:

CONCLUSIONS

- The EIA study reveals that the project is economically viable, socially acceptable and environment friendly.
- It will generate additional jobs during construction and operation phases.
- The proponent has committed to implement the project in the environment friendly manner.
- M/s Crystolite Pharmaceuticals intends to register the project with local Government.
- M/s Crystolite Pharmaceuticals has prepared and implemented very comprehensive Emergency Preparedness and Response Standard Operating Procedures.
- M/s Crystolite Pharmaceuticals has prepared and implemented very comprehensive Security and Fire Fighting Standards Operating Procedures.

RECOMMENDATIONS

- In view of the comprehensive screening process and findings of the present study there is no need of conducting further investigations.
- Tree plantation inside the unit and near the unit is recommended.
- The untreated wastewater will not be reused for irrigating the vegetation and lawns.
- High standards of bio-security and safety will be enforced during operation stage. Safety of the workers will be top priority for the management.
- The management of M/s Crystolite Pharmaceuticals will continue to assist the local communities as a corporate/social responsibility.

- The present EIA report is enough to meet the administrative and legal framework. Therefore, the environmental approval may be accorded for the present project.

ANNEXURE-A

TOR'S

TERM of REFERENCES (TORs)

Environmental Impact Assessment Study

M/s Crystolite Pharmaceuticals

Located at

Plot # 1 & 2, street s-2, national industrial zone, Rawat, Islamabad,
Pakistan

TERM OF REFERNCES

These terms of reference are being submitted for the subject EIA study under 5 (f) of policy and procedure for the filing, review, and approval of environmental assessment. These TORs of EIA have been prepared by the environmental consultants, in consultation with the project proponent.

INTRODUCTION OF PROJECT:

The proposed project is proposed construction of pharmaceutical unit under the name of M/s Crystolite Pharmaceuticals located at Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan, over an area of 21600 SFT. Covered area of plot is 12985 SFT and open area of plot is 8615 SFT. The Production capacity of the project will be approx., 6-8 lac Packs per month. Total cost of the project will be approx. 20 crores.

Name of proponent

Name: Mr. Ali Raza

CNIC# 33104-2121634-1

Mailing Address: Plot # 1 & 2, street S-2, National Industrial zone, Rawat, Islamabad, Pakistan

Environmental Consultant

Mr. Ali Raza has appointed the Pak Green Enviro Engineering (PVT.) LTD. as a Consultant for the subject project to conduct the EIA M/S Pak Green Enviro Engineering (PVT.) LTD. will be called as "Consultant" and M/S Crystolite Pharmaceuticals as the "Client".

The objective of the EIA study

The Objective of the study includes Compliance with section 12 of PEPA 1997 (Amended 2012) & PEQS.

Purpose of the EIA

The key objectives of the EIA are to:

- Document the ecological and socioeconomic baseline conditions of the study area and the affected communities
- Inform and obtain input from stakeholders, (e.g., governmental authorities, the public, and indigenous communities) and capture their relevant issues and concerns
- Assess in detail the environmental, social, and health impacts that would result from the Project

- Identify environmental and social mitigation measures to address the impacts identified
- Develop the EMPs as discussed above, based on the mitigation measures developed in the EIA
- Meet the requirements or recommendations of the applicable national Environmental Laws and Guidelines

Scope of Services

1. Review of existing regulatory framework
 - 1.1 Laws and Regulations
 - 1.2 National and International Guidelines and Policy
 - 1.3 Guidelines of Labor & Human Resource Department
 - 1.4 Punjab Local Government Ordinance
2. Methodology for carrying out this study
 - 2.1 Project Description
 - 2.2 Site Selection
 - 2.3 Project Alternatives
3. Process Description
 - 3.1. Detailed review of the processes
 - 3.2 Design Parameters
 - 3.3 Details related to Plant and Equipment.
4. Environmental profile of the environmental study area
 - 4.1 Climatology
 - 4.2 Geographical features
 - 4.3 Geological and Hydrological features
 - 3.5.4 Historical review
 - 3.5.5 Land Use
 - 3.5.6 Ecology, i.e. Flora and Fauna etc.

- 3.6 Analysis of EPA required environmental parameters
 - 3.6.1 Sampling for Air, Water, and Noise Level
- 3.7 Investigate Socio-Economic and Socio-Environmental aspects and cultural values within and around the operating facility
 - 3.7.1 Cultural and Social Values
 - 3.7.2 Interviews from different groups
- 3.8 Development activities and Waste Management
- 3.9 Identify and evaluate major environmental impacts
- 3.10 Identify mitigation measures and develop Environmental Management and Monitoring plan
- 3.11 Conclusions based on the study conducted for this EIA/EAR
- 3.12 1-2 Site Visits for data acquisition
- 3.13 Environmental Monitoring plan
- 3.14 Preparation of Lab Analysis Report
- 3.15 Preparation of Environmental Management Plan EMP
- 3.16 Briefing & Presentation to the Expert Committee in the EPA Punjab.
- 3.17 Reply to technical Environmental Objections/Review

CLIENT RESPONSIBILITY

- Proponent will be responsible to nominate a senior officer as Coordinator who will be responsible for all coordination activities as required by the Consultants and to whom the Consultants will refer for information and assistance. All correspondence between the Consultants and the CLIENT will be routed through the Coordinator
- Consultants will require free access to all relevant information available with the Client
- The report developed for the CLIENT shall be the property of the CLIENT and the Consultants shall adhere to confidentiality morally as well as legally.
- Client will provide relevant documents as:
 - Signed application on company letter head
 - Pay Order in favor of DG EPA as review fee 30,000/-
 - Undertaking on Stamp Paper as per EPA Format
 - Affidavit on Stamp Paper as per EPA Format
 - Copy of NIC of proponent
 - Dually filled and Sign Schedule IV
 - Details of firefighting Equipment's
 - Layout Maps of the project
 - Other NOCS/Certificates from other concerned departments (if any)
 - Any other relevant documents/details required by the consultant.

Signatures:



Environmental Consultant

Pak Green Enviro-Engineering Pvt. LTD.

Signatures:



Client: ALI RAZA

M/s CRYSTOLITE PHARMACEUTICALS



ANNEXURE-B

CNIC AND OTHER DOCUMENTS



PAKISTAN National Identity Card

Name
Ali Raza



Father's Name
Syed Mansoor Ali



Gender / Country of Origin
M Pakistan

Monthly Number 331042172834-1	Date of Birth 10.05.1975
Date of Issue 16.05.2014	Date of Expiry 16.05.2024

Holder's Signature



گمشدہ کارڈ ملنے پر قریبی ایئر بکس میں ڈال دیں



PAKISTAN National Identity Card

Name
Haris Raza



Father's Name
Sohail Ahmed



Gender / Country of Origin
M Pakistan

Monthly Number 61105-0407140-4	Date of Birth 05.05.1995
Date of Issue 16.02.2014	Date of Expiry 16.02.2024

Holder's Signature



گمشدہ کارڈ ملنے پر قریبی ایئر بکس میں ڈال دیں



PAKISTAN National Identity Card

Name
Ali Muhammad Ullah



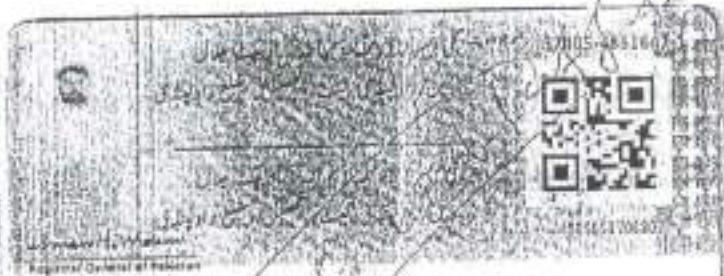
Father's Name
Muhammad Aslam



Gender / Country of Origin
M Pakistan

Monthly Number 37105-4861647-9	Date of Birth 27.03.1990
Date of Issue 08.08.2020	Date of Expiry 08.08.2030

Holder's Signature



گمشدہ کارڈ ملنے پر قریبی ایئر بکس میں ڈال دیں

RCCI INDUSTRIAL ESTATE

PLOT ALLOTMENT CERTIFICATE

REG No. RIE-2503

Serial No. ...2765..

Certified that

ALI RAZA

HOUSE # 326 32 # 34-E

SECTOR 1-9/4 ISLAMABAD

is hereby allotted plot no 1.2 measuring 750 sq yds
located on road 5-2

(Allotment conditions overleaf)

Station : Rawalpindi

Date 17-11-09

(EJAZ MEHMOOD)

Managing Director
Crescent Developers (Pvt) Ltd

Khan Chamber 60 - Cantt. Road Rawalpindi
UAN- 92-51-111-283-789 Fax 051- 5515779

ACKNOWLEDGEMENT/ RENUNCIATION

Serial No. ...2765

I ...ALI RAZA

do hereby renunciate
this allotment letter as
numbered above and
request that the title
deed be executed on
the following name:-

SIGNATURE
REG No. 2503



Crescent Developers (PVT) Limited

Khan Chamber, 60 Canning Road, Saddar, Rawalpindi, Pakistan

UAN: 92-51-111-289-289, Fax: 92-51-5515779

E-mail: info@cres_dev.com Website: www.cres_dev.com

RCCI INDUSTRIAL ESTATE **POSSESSION LETTER**

REG#: RIE-2503

Serial #: 503

Certified that

1. **Ali Raza** resident of **House # 326, St # 34-E, Sector I-9/4 Islamabad** is hereby authorized to get the possession of plot No.1, 2, measuring **2400 sq yds.**, located at **S-2** in **RCCI Industrial Estate Rawat Distt: Rawalpindi**.
2. **RCCI Industrial Estate, Rawat, building bye-laws** are attached (Price Rs. 300/-). You are requested to abide by these laws before/after construction of your industry.
3. After getting the possession of plot, construction of boundary wall is to be started within one month.
4. A separate permission letter for construction of building will be issued by this office after approval of building plan.
5. This possession letter is valid for one month from the date of issuance.
6. Possession/Demarcation fee Rupees Three thousand Received/Not Received.

Dated: April 2010


(EJAZ MEHMOOD)
Managing Director

Book No.B 13208

Serial No.B 1320793

MEMBERSHIP CERTIFICATE

Name & address of Chamber **Islamabad Chamber of Commerce & Industry**
Association **Atwan-e-Sanat-o-Tijarat Road, G-8/1, Islamabad.**
Tel: +92-51-2261175-76, 2253145 Fax: +92-51-2252950
Email: icci@brain.net.pk; info@icci.com.pk; www.icci.com.pk
(Affiliated with the Federation of Pakistan Chambers of Commerce & Industry)

CERTIFIED that **Ms. CRYSTOLITE PHARMACEUTICALS**

(name and address of Member Firm / Company)

PLOT #.1&2, S-2, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD

G.S.T. No. **07-01-3004-055-64** N.T.N. No. **-1290548-B**

is a member of this Chamber **CM-1427**
Association

THIS CERTIFICATE shall be valid upto the **31st March 2024**... unless
Renew Membership before 31st March 2024 *(date)*

otherwise notified to the NTN / GST Registration authority / Scheduled Bank
concerned.



Given on this **16th** day of **Mar** **20 23**

Signature of Secretary General **Majid Shabbir**

Countersigned by **Ahsan Zafar Bakhtawar**
President

ANNEXURE-C

GOOGLE EARTH MAP

CRYSTOLITE PHARMACEUTICALS

33°31'12.60"N
73°14'19.95"E

Legend

- Madina Glass Processing Unit 2
- Nusrat Farooq Flour General



ANNEXURE-D

LAB REPORTS (AIR, WATER, NOISE)



PAK GREEN ENVIRO-ENGINEERING (Pvt.) Ltd.

ISO/IEC 17025:2017 Accredited Testing Lab, ISO 9001:2015, ISO 14001:2015, ISO 45001:2018

Head Office: 46-M, Gulberg III, Lahore-Pakistan. Ph: +9242-35441444 Cell: 0303-4442334

PGG/IMS/FF/063

Rev.#02

Rev date: 04-09-23

EPA Certified

TEST REPORT

Ref #: PGL/LAB/2024-3299/AA

Issue date: 05-Mar-24

Name of Industry/Client:
Address of monitoring site:

Crystolite Pharmaceutical
Plot #1&2, Street S-2, National Industrial Zone, Rawat,
Islamabad, Pakistan

Nature of Monitoring:
Monitoring Location:
Monitoring Instrument:
Monitoring Date:

Ambient Air
Main Gate
AQMS
29-Feb-24

Date of completion of sampling:
Validated by EPA Representative:

29-Feb-24 to 30-Feb-24
M. Amin Baig, RO EPA (Lab), Rawalpindi

Results:

Parameters	CO	NO	NO ₂	SO ₂	PM ₁₀	PM _{2.5}
	mg/m ³	µg/m ³	µg/m ³	µg/m ³	ug/m ³	ug/m ³
Methodology	Non-Dispersive Infrared Absorption (NDIR)	Reduced Pressure Chemiluminescence (CLD)	Reduced Pressure Chemiluminescence (CLD)	UV Fluorescence (UVF)	Integrated Sampling Technique	Integrated Sampling Technique
Results	2.03	21.67	55.14	9.12	163.7*	57.4*
NEQS for Ambient Air	05 8-Hrs	40 24-Hrs	80 24-Hrs	120 24-Hrs	150 24-Hrs	35 24-Hrs

End of Report

NEQS: National Environmental Quality Standards

Remarks: Parameters with * exceeding NEQS Limit.

Terms & Conditions:

- Analysis was conducted on the request of project proponent for IEE/ELA Baseline study.
- Report cannot be used regarding compliance of any complaint, EPO or any other court case.
- This report should be reproduced as a whole and not in parts.
- The responsibility of the ethical use of the results reported in this report lies with the client. Consequently, the laboratory is absolved of its responsibility for any claim that may result through the use by the client or others of the results appearing in this report.
- The left-over sample (if so available) shall be retained for fifteen days after the issuance of the report unless otherwise negotiated between the client and the laboratory.
- The report is not valid for any negotiations.

Field Analyst	Chief Analyst	Laboratory Incharge



Page 1 of 1





PAK GREEN ENVIRO-ENGINEERING (Pvt.) Ltd.

ISO/IEC 17025:2017 Accredited Testing Lab, ISO 9001:2015, ISO 14001:2015, ISO 45001:2018

Head Office: 46-M, Gulberg III, Lahore-Pakistan. Ph: +9242-35441444 Cell: 0303-4442334

PGG/IMS/FF/063

Rev.#02

Rev date: 04-09-23

EPA Certified

TEST REPORT

Ref #: PGL/LAB/2024-3300/NL

Issue date: 05-Mar-24

Name of Industry/Client:
Address of monitoring site:

Crystolite Pharmaceutical
Plot #1&2, Street S-2, National Industrial Zone, Rawat,
Islamabad, Pakistan

Nature of Monitoring:
Monitoring Time:
Monitoring Instrument:
Monitoring Date:

Noise Level
Real Time
Land TEK SL 5868-P
29-Feb-24

Validated by EPA Representative:

M. Amin Baig, RO EPA (Lab), Rawalpindi

Results:

Sr. No.	Locations	Equivalent Noise Level dB (A)
1.	Point-01: North Side	67.8
2.	Point-02: West Side	71.5
3.	Point-03: South Side	69.0
4.	Point-04: East Side	65.4
NEQS (Day Time Industrial Area)		75 dB(A)

End of Report

NEQS: National Environmental Quality Standards

Remarks: Noise level at all points are not in compliance with NEQs Limit.

Terms & Conditions:

- Analysis was conducted on the request of project proponent for IEE/EIA Baseline study.
- Report cannot be used regarding compliance of any complaint, EPO or any other court case.
- This report should be reproduced as a whole and not in parts.
- The responsibility of the ethical use of the results reported in this report lies with the client. Consequently, the laboratory is absolved of its responsibility for any claim that may result through the use by the client or others of the results appearing in this report.
- The left-over sample (if so available) shall be retained for fifteen days after the issuance of the report unless otherwise negotiated between the client and the laboratory.
- The report is not valid for any negotiations.

Field Analyst	Chief Analyst	Laboratory Incharge





PAK GREEN ENVIRO-ENGINEERING (Pvt.) Ltd.

ISO/IEC 17025:2017 Accredited Testing Lab, ISO 9001:2015, ISO 14001:2015, ISO 45001:2018

Head Office: 46-M, Gulberg III, Lahore-Pakistan. Ph: +9242-35441444 Cell: 0303-4442334

EPA Certified

PGG/IMS/FF/159

Rev.000

Rev date: 04-09-23

TEST REPORT

Ref #: PGL/LAB/2024-3301/GW

Issue date: 05-Mar-24

Name of Industry/Client:
Address of monitoring site:

Crystolite Pharmaceutical
Plot #142, Street S-2, National Industrial Zone, Rawat,
Islamabad, Pakistan

Nature of Sample:

Ground Water

Sampling By:

Pak Green Laboratories

Sample Source:

Motor Pump

Sample Code:

GW-352

Date of sampling:

29-Feb-24

Sample Receiving Date:

29-Feb-24

Testing Facility:

Pak Green Laboratories

Testing Date:

29-Feb-24 to 04-Mar-24

Validated by EPA Representative:

M. Amin Baig, RO EPA (Lab), Rawalpindi

Results:

Sr. No.	Parameters	Unit	WHO	NEQS	Method / Technique	Results
1.	Taste	-	Non-Objectionable / Acceptable	Non-Objectionable / Acceptable	APHA-2160 C	Non-Objectionable
2.	Odor	-	Non-Objectionable / Acceptable	Non-Objectionable / Acceptable	APHA-2150 B	Non-Objectionable
3.	Color	TCU	≤ 15	≤ 15	APHA-2120 C	0.000
4.	Turbidity	NTU	< 5	< 5	APHA-2130 B	0.30
5.	Total Hardness [^]	mg/L	-	< 500	APHA-2340 C	20
6.	Total Dissolved Solids [^]	mg/L	< 1000	< 1000	APHA-2540 C	1460*
7.	pH [^]	-	6.5-8.5	6.5-8.5	APHA-4500-H ⁺ B	8.133 at 23.0°C
8.	Chloride (Cl ⁻) [^]	mg/L	250	< 250	APHA-4500-Cl ⁻ B	382*
9.	Electrical Conductivity (EC) [^]	µS/cm	-	-	APHA-2510 B	2207
10.	Sodium (Na) [^]	mg/L	-	-	APHA-3111 B	110.9867

End of Report

NEQS: National Environmental Quality Standards

WHO: World Health Organization

[^] PNAC Accredited

Remarks: Parameters with * are not in compliance with the NEQS Limit.

Terms & Conditions:

- Analysis was conducted on the request of project proponent for IEE/EIA baseline study.
- Report cannot be used to comply with any complaint, EPO, or other court case.
- This report should be reproduced as a whole and not in parts.
- The values represent the sample conditions when sampling/monitoring was carried out.
- The Environmental Conditions while performing testing activities are (Temp=22.0-23.8°C) and (RH=51.9-54.9%)
- The Sampling was done as per the sampling and preservation protocol method APHA 1050-B&C
- The responsibility of the ethical use of the results reported in this report lies with the client.
- The leftover sample (if so available) shall be retained for fifteen days after the issuance of the report unless otherwise negotiated between the client and the laboratory.
- The report is not valid for any negotiations.
- Dually calibrated instruments were used during monitoring and testing activities.

Lab. Analyst	Chief Analyst	Laboratory Incharge





Validation for Wastewater & Drinking Water

Facility / Project Name & Address	Cargill Pharmaceuticals		Sampling Point	C/W-01	
Phone	At plot # 132, Street S-2, National Industrial Zone, Rawat, Islamabad		Drinking Water (W) Treatment Facility		
Waste Water (WW) Treatment Facility					
Primary Secondary Tertiary NA					
Total WW collected Sample N/A			Total Collected Drinking water samples 2		
Sample Tag for testing parameter is assigned on sample container			Yes	NO	NA
Sample is preserved properly for each testing parameter			Yes	NO	NA
Sample size is adequate for testing the target parameters			Yes	NO	NA
Wastewater Flow Measurement performed to ensure sample representativeness					
Fig. of Waste Water outlets	Waste Water Flow m ³ /hr from each outlet (Optional)	Water Inlet m ³ /hr (Optional)	Water Mass balance compiled during sampling (Optional)	Sample Type	
N/A	N/A	N/A	Yes	NO	Composite
Parameter	Matrix	Container	Sample Size	Preservation	Yes NO NA
Coliform, Total or Fecal	W	Sample Container	100 mL	Refrigerate 4 C	
Coliform, Total or Fecal, Chlorinated Water	W	Sealable Container	100 mL	2.003% Thiosulphate & cooled 6 C	✓
Color, Turbidity	W	P.O	500 mL	Cool 6 C	✓
Hardness, Total	W	P.O	500 mL	HNO ₃ to pH < 2	✓
Ammonia, Nitrate + Nitrite, Phosphate, Cyanide, Oil & Grease, COD, BOD	W	P.O	1000 mL	HNO ₃ to pH < 2, Cool 6C	
Metals, General	W	P.O Rinsed 1:1 HNO ₃	500 mL	HNO ₃ to pH < 2	
Cyanide, Total	W	P.O	500 mL	NaOH to pH > 12, Cool 6C	
Pesticides, General	W	Glass	1 Liter	Cool 6 C	
Field Parameters*					
Field parameter		pH meter, Model/Make	Measurement Method	Calibrated in Field	Measured value
pH		HS-212	APHA. 4500-P	Yes	6.0
Temp					
Cl					

* Field testing parameters only be validated by PAS, ROD, DO (Labs)
Remarks for Sample Quality (if any):

Signature

Name of EPA Officer with office Address

Inspector / PAS / ROD, Muhammad Aslam
Researcher
Environmental Protection Agency
Govt. of the Punjab, Rawalpindi

Dated:

29-02-2024

Signature

Name of Assistant / Deputy Analyst

With Name of Private Lab along with Address





Validation for Stack & Ambient Monitoring / Sampling

Emission Monitoring under CEM-34 or OTE-29			
Facility Name & Address	Crystallite Pharmaceuticals, Plot No. 182, Street 5-2, National Industrial Zone, Rawat, Islamabad		
Phone	Baseline Study		
Industry Category	Baseline Study		
Analyser Model & Make: Testo 350			
Average stack emission values of CO, NOx (in mg/m ³)			
Excess Air / Excess Oxygen (Vagel):	Yes	No	NA
Analyzer exposed for Ramp-Up phase to the sample gas for 5 minutes	Yes	No	NA
Analyzer flow rate and EC temperature monitored during calibration and testing	Yes	No	NA
Test Date Phase of sample gas recorded with 35 second interval	Yes	No	NA
All key requirements to ensure QA/QC complied for said EPA approved Method	Yes	No	NA
Particulate Matter (PM) Monitoring / Sampling under USEPA Method 5 / 17			
Model & Make of Iso-Kinetic PM Assembly	Yes	No	NA
The PM sampling train is complete as per Method 5 & 17	Yes	No	NA
Leak Test performed prior to sampling	Yes	No	NA
Field data sheet for PM Sampling filled during PM sampling	Yes	No	NA
Data for determining of "K" factor & DGM "Y" factor filled during sampling	Yes	No	NA
All method key requirements during sampling were complied to ensure QA/QC	Yes	No	NA
Filter of Particulate matter is suitable for metal testing	Yes	No	NA
SOx sampling as per Method 8 (Thorn indicator Method)	Yes	No	NA
The right absorbent solution are available for SOx sampling	Yes	No	NA
The equipment is capable to maintain flow rate @ 2.0 LPM or as per method 8 requirement	Yes	No	NA
Sampling for SOx is performed as per method			
Ambient Air Quality Monitoring by Automatic Monitor for CO, O ₃ , SO ₂ , NOx, PM2.5 & PM10	Yes	No	NA
In case of continuous monitoring at a site, One Point QC Check Single analyzer & Zero/span check is performed every 14 days	Yes	No	NA
The CE of NOx analyzer is ensured to be maintained within 95% - 104.1%	Yes	No	NA
Zero/span check is performed prior to starting ambient monitoring	Yes	No	NA
All key requirements for Critical & Operational Criteria for ambient air monitoring by automatic monitors were complied during monitoring	Yes	No	NA
The monitoring techniques of monitors comply PQOS	Yes	No	NA
Ambient Air Sampling of SPm, PM10, Pb by High Volume Sampler	Yes	No	NA
In case of Sampling for SPm through samplers, the flow rate of sampler comply PQOS (3.1 m ³ /min)	Yes	No	NA
Calibration of Sampler performed prior to sampling	Yes	No	NA
Vehicular Emissions & Noise Measurement			
Sampling of Vehicle emissions and noise measurement have been performed as per method and SOPs	Yes	No	NA

Remarks (if Any):

Signature

Name of EPA Officer with office address
RAE / ROs / DD(Lab)

Muhammad Amin
Research Officer
Environmental Protection Agency
Govt. of the Punjab, Rawalpindi

Dated:

29-02-2024

Aslam Haider Analyst

Name of Assistant / Deputy Analyst, Analyst
with Name of Private Lab along with Address

ANNEXURE-E

LAYOUT MAP OF PROPOSED SITE

SCHEDULE OF OPENING

S.N.	TYPE	SIZE	REMARKS
01	DOOR	9'0" X 7'0"	FRONT DOOR
02	DOOR	9'0" X 7'0"	FRONT DOOR
03	DOOR	9'0" X 7'0"	FRONT DOOR
04	DOOR	9'0" X 7'0"	FRONT DOOR
05	DOOR	9'0" X 7'0"	FRONT DOOR
06	DOOR	9'0" X 7'0"	FRONT DOOR
07	DOOR	9'0" X 7'0"	FRONT DOOR
08	DOOR	9'0" X 7'0"	FRONT DOOR
09	DOOR	9'0" X 7'0"	FRONT DOOR
10	DOOR	9'0" X 7'0"	FRONT DOOR
11	DOOR	9'0" X 7'0"	FRONT DOOR
12	DOOR	9'0" X 7'0"	FRONT DOOR
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98	DOOR	9'0" X 7'0"	FRONT DOOR
99	DOOR	9'0" X 7'0"	FRONT DOOR
100	DOOR	9'0" X 7'0"	FRONT DOOR

SCHEDULE OF AREA

TOTAL AREA OF PLOT	= 144' x 102' = 14688 SFT
COVERED AREA OF PLOT	= 12985/21600 X 100 = 60.12%
OPEN AREA OF PLOT	= 8615/21600 X 100 = 39.88%

COVERED / OPEN AREA RATIO

COVERED AREA RATIO	= 12985/21600 X 100 = 60.12%
OPEN AREA RATIO	= 8615/21600 X 100 = 39.88%

DETAIL OF TECHNICAL AREA (SECTION WISE)

Q.C LAB	= 672.00	SFT
RAW MATERIAL STORE	= 1052.00	SFT
FINISH GOODS STORE	= 501.11	SFT
PACKING MATERIAL STORE	= 611.00	SFT
SERVICE AREA	= 366.00	SFT
PRODUCTION RECORD ROOM	= 226.20	SFT
GENERAL TABLET & SACHET SECTION	= 1301.60	SFT
STERILIZATION & LOTION SECTION	= 1345.00	SFT
GENERAL CAPSULE SECTION	= 413.00	SFT
SOFT GELATIN CAPSULE	= 390.00	SFT
LIQUID SYRUP SECTION	= 687.33	SFT
GENERAL TOPICALS SECTION	= 705.00	SFT
TOTALS PACKING HALL	= 322.00	SFT
MALE CHANGE ROOM	= 289.00	SFT
FEMALE CHANGE ROOM	= 341.00	SFT
ENTRANCE LOBBY	= 288.00	SFT
EXECUTIVE ENTRANCE	= 119.00	SFT
GENERAL PACKING HALL	= 614.79	SFT

DETAIL OF FIRST FLOOR & MAINTENANCE FLOOR

ADMIN BLOCK	= 1300.00	SFT
WATER TREATMENT	= 250.00	SFT
MAINTENANCE FLOOR AREA	= 7817.00	SFT

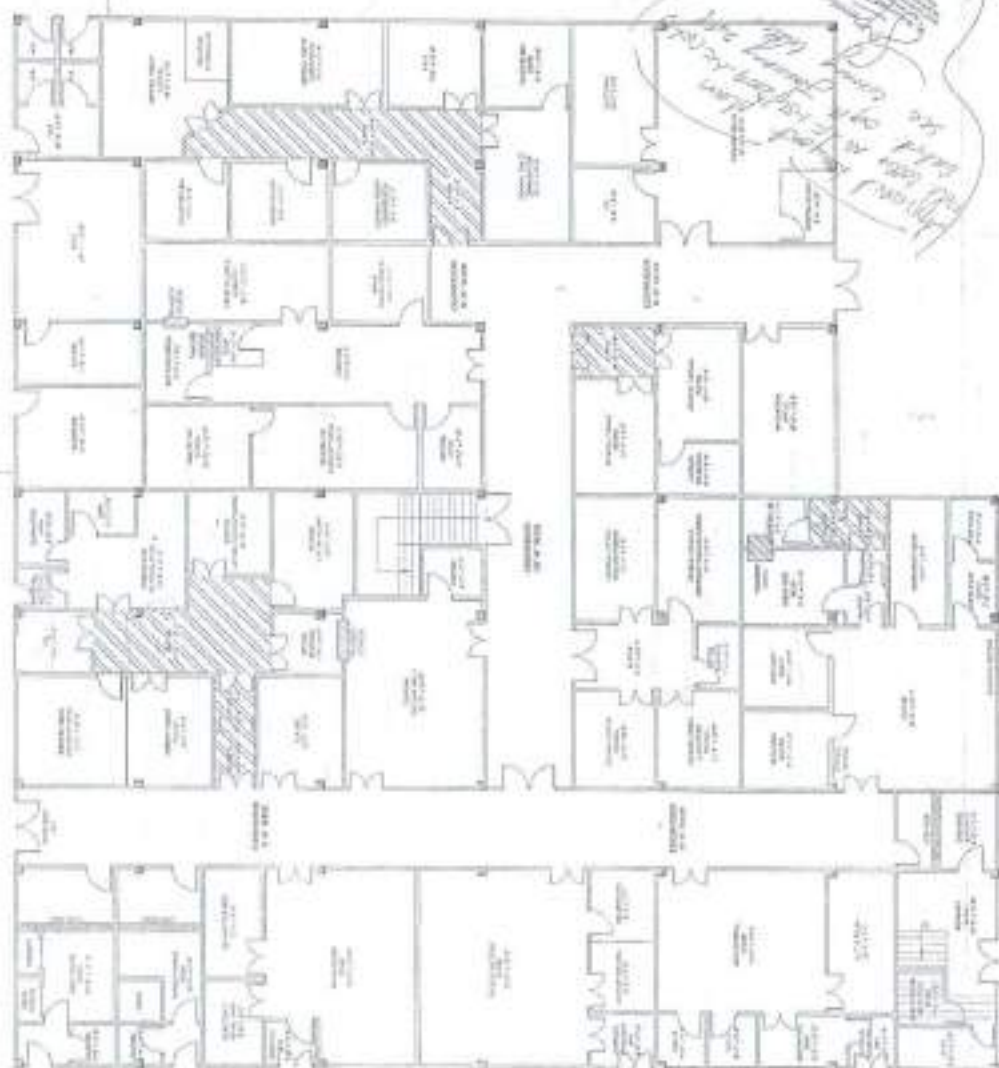
CRYSTOLITE PHARMACEUTICALS
SITUATED AT PLOT NO. 1 & 2,
ROAD S-2, RCC INDUSTRIAL AREA
ISLAMABAD

CHIEF EXECUTIVE

MR. ALI RAZA

OWNER'S SIGNATURE

GROUND FLOOR PLAN



ANNEXURE-F

LIST OF RAW MATERIAL

Crystolite Pharmaceuticals



RAW MATERIAL (SOURCE/ QUANTIFICATION PER BATCH)

S.No	RAW MATERIAL	SUPPLIER NAME	AVERAGE QTY PER BATCH
1.	Acitretin	Chongqing Huapont Shengchem Pharma	2.257 kg
2.	Acyclovir	Zhejiang Zhebei Pharmaceutical Co Ltd China	2.59 kg
3.	Adapalene	Aarti Industries Ltd. India Bal Pharma Limited	0.0907 kg
4.	Apremilast	Glenmark Life Sciences India Guangdong Xinqiang Pharma China	3.994 kg
5.	Azathioprine	Fermion OY Finland Rakshit Pharmaceuticals India	12.588 kg
6.	Azithromycin Dihydrate	Zhejiang Guobang Pharmaceutical Co., Ltd	15.519 kg 25.86 kg
7.	Betamethasone Dipropionate	Symbiotica (Malaysia) Haleyon Lab Pvt Ltd India	.380 kg
8.	Betamethasone Valerate	Symbiotica (Malaysia) Anuh Pharmaceutical Ltd India	0.110 kg
9.	Calcipotriol Monohydrate	Chongqing Huapont Shengchem Pharma	0.0047 kg
10.	Carbamazepine	Bajaj Health Care Limited India	
11.	Cholecalciferol (vitamin D3) 40 Million IU/g	Zhejiang Nhu Company Ltd	0.125 kg
12.	Ciclopirox Olamine	Shanghai Pharma Group	3.63 kg
13.	Ciprofloxacin HCl (Granular)	Pharmagen Limited CITI Pharma	28.997 kg
14.	Clindamycin Phosphate	Topfond Pharmaceutical Co., Ltd, China Zhejiang Hisoar Pharmaceuticals Co.,Ltd	2.59 kg
15.	Clobetasol Propionate	Symbiotica (Malaysia) Haleyon Lab India	0.1814 kg
16.	Clotrimazole	Srikem Labs Pvt Ltd India Haleyon Lab Pvt Ltd India Stride Industries India	4.918 kg
17.	Clomiphene Citrate	Bioxera Phamaceutical Pvt Ltd India	0.503 kg

Crystolite Pharmaceuticals



RAW MATERIAL (SOURCE/ QUANTIFICATION PER BATCH)

18.	Coal tar	Al burque International (National Trading)	7.20 kg
19.	Daclatasvir Dihydrochloride	Suli Pharmaceutical China	
20.	Dapsone	Nuray Chemicals India	5.016 kg
21.	Dexlansoprazole Pellets 22.5%	Vision Pharmaceuticals, Islamabad	16.27 kg
22.	Desloratadine	Glenmerk Life Sciences India	0.25 kg
23.	Dioctahedral smectite	Shandong Xianhe phc china	64.44 kg
24.	Divalproex sodium	Varahi International India	16.21 kg
25.	Domperidone	Vasuda Pharma India	
26.	Domperidone Maleate	Vasuda Pharma India	1.274 kg
27.	Doxycycline Hyclate	Kaifeng Pharmaceutical China Hebei Dongfeng Pharma China	18.13 kg
28.	Duloxetine pellets 17.65%	Surge Laboratories	1.72 kg
29.	Ebastine	Bal Pharma Limited	0.8054 kg
30.	Ecitalopram Oxalate	Synergene Active Ingredients Pvt Ltd. India Shodhana Laboratories Private Limited India	
31.	Effornithine HCl Monohydrate	Rusan Pharmaceuticals India	3.89 kg
32.	Erythromycin	Haleyon Lab Pvt Ltd India Linaria Chemicals (Thailand)Ltd	2.095 kg
33.	Esomeprazole Mg 22.5% w/w Pellets BP	Vision Pharmaceuticals Alphamed Formulation Pvt Ltd India	7.466 kg
34.	Esomeprazole Mg 8.5% w/w Pellets BP	Vision Pharmaceuticals	
35.	Famciclovir	Shanghai Pharma Group Changhou Kony Pharmaceutical Co.Ltd China	9.99 kg
36.	Fexofenadine HCl	Vasuda Pharma India Ind-Swift Labouritories Limited Tagoor Labs India	12.93 kg
37.	Fluconazole	Synergene Active Ingredients Pvt Ltd. India	1.505 kg
38.	Fluocinolone Acetonide	Farmabios Spa Via Pavia Gropeeli Italy	0.015 kg
39.	Fluticasone Propionate	Micro Orgo Chem India Aarti Industries Ltd. India	0.050 kg

Crystolite Pharmaceuticals



RAW MATERIAL (SOURCE/ QUANTIFICATION PER BATCH)

		Shakti Life Science Private Limited India	
40.	Fusidic acid	Ereroz S.A . Spain M/s Joyang Laboratories china Shandong Gede Biological Technology Co.,Ltd China	1.86 kg
41.	Fosfomycin Trometamol	Hunan Warrant Pharma China	
42.	Finasteride	Hubei Gedian Humanwell Pharmaceutical Co	0.180 kg
43.	Halobetasol Propionate	Maharshi Pharma Chem (Pvt) Ltd India	0.045 kg
44.	Hydrocortisone Acetate	Symbiotica (Malaysia) Henan Lihua Pharmaceutical China	0.903 kg
45.	Hydrocortisone Base	Zhejiang Xianju Pharmaceutical China Henan Lihua Pharmaceutical China	2.40 kg
46.	Hydroquinone	Srikem Labs Pvt Ltd.India Guandong Renren Kan Pharmaceutical Co Lt	6.003 kg
47.	Isotretinoin	Chongqing Huapont Shengchem Pharma	2.005 kg
48.	Ketotifen Fumarate	M/S. Zhejiang Huahai Pharmaceutical Co., Ltd.,	
49.	Ketoconazole	Aarti Industries Ltd. India	9.65 kg
50.	Lactic acid	Hangzhou Zhongbao China Wuhan Sanjiang Space Good Biotech China	15.59 kg
51.	Ledipasvir Copovidone	Suli Pharmaceutical China	
52.	Letrozole	Jiangsu Hengrui Medicine Co Ltd China	0.098 kg
53.	Levetiracetam	Hangzhou Huadong Medicine China Dhanuka Laboratories Ltd India Unichem	6.022 kg
54.	Levocetirizine DI HCl	Symed Labs Limited India	0.500 kg
55.	Levofloxacin Hemihydrate	Pharmagen Limited Shangyu Jingxin Pharmaceutical China Zhejiang East Asia	20.23 kg
56.	Lignocaine Base (Lidocaine)	Gufic Biosciences Ltd india	6.33 kg
57.	Linezolid	Optrix Laboratories Pvt. Ltd., (M/S Optimus Drugs Private Limited)	24.987 kg
58.	Loratadine	Vasuda Pharma India	1.204 kg
59.	Mebeverine HCl	Ra Chem Pharma Ltd India	
60.	Methyl Prednisolone Aceponate	Symbiotica (Malaysia) Maharishi Pharma Chem India	0.0906 kg
61.	Methotrexate Sodium	M/S Zhejiang Davi Pharmaceutical Co., Ltd.	0.608 kg

Crystolite Pharmaceuticals



RAW MATERIAL (SOURCE/ QUANTIFICATION PER BATCH)

		China	
62.	Mometasone Furoate	Micro Orgo Chem India Maharishi Pharma Chem India	0.241 kg
63.	Miconazole Nitrate	Gulic Biosciences Limited	3.607 kg
64.	Minoxidil	Kumar Organic Products India Vpl Chemicals Pvt Ltd India	24.208 kg
65.	Mirtazapine hemihydrate	Megafine Pharma (P) Ltd . India	
66.	Montelukast sodium	Metrochem API Ltd	0.44 kg
67.	Moxifloxacin Hydrochloride	Shankus Pharmaceuticals Shreejee Labs India Zhejiang Goubang China	6.316 kg
68.	Mupirocin	Concard Biotech Ltd. India Hangzhou Zhongmei Huadong China	1.85 kg
69.	Omeprazole Powder	Everest Organics Ltd India	0.807 kg
70.	Omeprazole 22.5% W/W Pellets	Vision Pharmaceuticals, Islamabad	4.98 kg
71.	Omeprazole 8.5% W/W Pellets	Vision Pharmaceuticals, Islamabad	9.90 kg
72.	Olanzapine	Smilax Laboratories Ltd. India	0.102 kg
73.	Orlistat pellets 50%	Alphamed Formulation Pvt Ltd India Surge labs	2.45 kg
74.	Quetiapine Fumarate USP	Ind-Swift Labouritories Limited	
75.	Pantoprazole pellets 22.5%	Vision Pharmaceuticals, Islamabad	7.499 kg
76.	Paroxetine HCl	Zhejiang Huisen Pharmaceutical Co., Ltd. China	
77.	PEG 3350	Avesta Pharma Pvt Ltd India	65.69 kg
78.	Permethrin	Srikem Labs Pvt Ltd.India Taa Health Care	18.15 kg
79.	Piracetam	Jiangxi Yuehua Pharmaceutical	48.25 kg
80.	Piroxicam Beta Cyclodextrin (Granular)	Kaifeng Pharmaceutical China	21.717 kg
81.	Prednicarbate	Symbiotica (Malaysia)	0.070 kg
82.	Pregabalin	Opatrix Laboratories Pvt. Ltd.,(M/S Optimus Drugs Private Limited)	1.58 kg
83.	Rabeprazole pellets 8.5%	Vision Pharmaceuticals, Islamabad	4.71 kg
84.	Risperidone	RPG Life Sciences Limited, India	0.040 kg

Crystolite Pharmaceuticals



RAW MATERIAL (SOURCE/ QUANTIFICATION PER BATCH)

85.	Salicylic Acid	Jqc (Huayin) Pharmaceutical China.	14.68 kg
86.	Sevelamer HCl	M/s Suleshvari Pharma, India.	
87.	Sodium Fusidate	Ereroz S.A . Spain M/s Joyang Laboratories China	1.82 kg
88.	Sertraline HCl	Amoli Organics Pvt. Limited, India	1.48 kg
89.	Sodium Bicarbonate	Toss enterprises	0.897 kg
90.	Sofosbuvir	Ruyuan Hee Pharma	
91.	Strontium Ranelate	Sunril Pharmaceuticals Pvt Ltd. India.	
92.	Tacrolimus monohydrate USP	Concord Biotech Ltd. India North China Pharmaceutical Huasheng Co.,	0.092 kg
93.	Tepantadol HCl	Precise Chemi Pharma India	1.75 kg
94.	Tenofovir Alafenamide Fumarate	Yichang HEC China	
95.	Tenofovir Disproxil Fumarate	Mangalam Drugs Organics Ltd India	
96.	Terbenafine HCl	Shandong Anhong Pharmaceutical Co., Ltd. China. Synergene Active Ingredients	144.156 kg
97.	Tazarotene	Chongqing Huapont Shengchem Pharma	0.090 kg
98.	Tetracaine	M/s Venkata Narayana Active Ingredients Pvt. Limited, India. Shandong Chenghui Shuangda Pharmaceutical Co., Ltd	6.33 kg
99.	Tretinoin	Chongqing Huapont Shengchem Pharma	0.075 kg
100.	Velpatasvir	Ruyuan HEC Pharma	
101.	Venlafaxine HCl	Suleshvari india	0.855 kg
102.	Vitamin E	Zhejiang Medicine Co., Ltd, China	40.754 kg
103.	Cinitapride Hydrogen Tartrate	Metrochem API India	
104.	Cyclosporine	North China Pharmaceutical Huasheng Co.,	2.034 kg
105.	Diclofenac Potassium	M/S Aarti Drugs Limited India	3.02 kg
106.	Diclofenac Sodium	M/S Aarti Drugs Limited India	1.006 kg
107.	Itopride	Ami Life Sciences India	0.954kg
108.	Iron III Hydroxide Poly Maltose	Chemi World Pvt Ltd	
109.	Rifaximin	Luohe Chief Pharmaceutical Co., Ltd	

RAW MATERIAL (SOURCE/ QUANTIFICATION PER BATCH)

ANNEXURE-G

LIST OF CHEMICALS

Crystolite Pharmaceuticals



LIST OF CHEMICALS

Document No.	CRY/ID/015
Effective Date:	23-05-2023
Revision No.	01
Next Revision Date:	MAY 2026
Controlled Copy No.	01

S.No	RAW MATERIAL
1.	Acitretin
2.	Acyclovir
3.	Adapalene
4.	Apremilast
5.	Azathioprine
6.	Azithromycin Dihydrate
7.	Betamethasone Dipropionate
8.	Betamethasone Valerate
9.	Calcipotriol Monohydrate
10.	Carbamazepine
11.	Cholecalciferol (vitamin D3) 40 Million IU/g
12.	Ciclopirox Olamine
13.	Ciprofloxacin HCl (Granular)
14.	Clindamycin Phosphate
15.	Clobetasol Propionate
16.	Clotrimazole
17.	Clomiphene Citrate
18.	Coal tar
19.	Daclatasvir Dihydrochloride
20.	Dapsone
21.	Dexlansoprazole Pellets 22.5%
22.	Desloratadine
23.	Dioctahedral smectite
24.	Divalproex sodium

Crystolite Pharmaceuticals



LIST OF CHEMICALS

Document No.	CRY/ID/015
Effective Date	23-05-2023
Revision No.	01
Next Revision Date	MAY 2026
Controlled Copy No.	01

25.	Domperidone
26.	Domperidone Maleate
27.	Doxycycline Hyclate
28.	Duloxetine pellets 17.65%
29.	Ebastine
30.	Ecitalopram Oxalate
31.	Eflornithine HCl Monohydrate
32.	Erythromycin
33.	Esomeprazole Mg 22.5% w/w Pellets BP
34.	Esomeprazole Mg 8.5% w/w Pellets BP
35.	Famciclovir
36.	Fexofenadine HCl
37.	Fluconazole
38.	Fluocinolone Acetonide
39.	Fluticasone Propionate
40.	Fusidic acid
41.	Fosfomycin Trometamol
42.	Finasteride
43.	Halobetasol Propionate
44.	Hydrocortisone Acetate
45.	Hydrocortisone Base
46.	Hydroquinone
47.	Isotretinoin
48.	Ketotifen Fumarate
49.	Ketoconazole
50.	Lactic acid
51.	Ledipasvir Copovidone
52.	Letrozole
53.	Levetiracetam
54.	Levocetirizine DI HCl

Crystolite Pharmaceuticals



LIST OF CHEMICALS

Document No.	CRY/ID/015
Effective Date:	23-05-2023
Revision No.	01
Next Revision Date	MAY 2026
Controlled Copy No.	01

55.	Levofloxacin Hemihydrate
56.	Lignocaine Base (Lidocaine)
57.	Linezolid
58.	Loratadine
59.	Mebeverine HCl
60.	Methyl Prednisolone Aceponate
61.	Methotrexate Sodium
62.	Mometasone Furoate
63.	Miconazole Nitrate
64.	Minoxidil
65.	Mirtazapine hemihydrate
66.	Montelukast sodium
67.	Moxifloxacin Hydrochloride
68.	Mupirocin
69.	Omeprazole Powder
70.	Omeprazole 22.5% W/W Pellets
71.	Omeprazole 8.5% W/W Pellets
72.	Olanzapine
73.	Orlistat pellets 50%
74.	Quetiapine Fumarate USP
75.	Pantoprazole pellets 22.5%
76.	Paroxetine HCl
77.	PEG 3350
78.	Permethrin
79.	Piracetam
80.	Piroxicam Beta Cyclodextrin (Granular)
81.	Prednicarbate
82.	Pregabalin
83.	Rabeprazole pellets 8.5%
84.	Risperidone

Crystolite Pharmaceuticals



LIST OF CHEMICALS

Document No.	CRY/ID/015
Effective Date	23-05-2023
Revision No.	01
Next Revision Date	MAY 2026
Controlled Copy No.	01

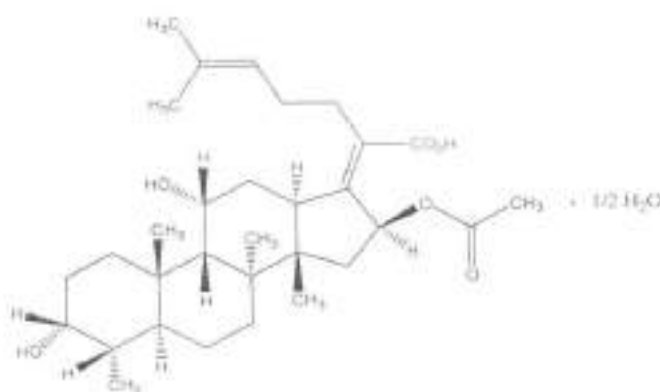
85.	Salicylic Acid
86.	Sevelamer HCl
87.	Sodium Fusidate
88.	Sertraline HCl
89.	Sodium Bicarbonate
90.	Sofosbuvir
91.	Strontium Ranelate
92.	Tacrolimus monohydrate USP
93.	Tepantadol HCl
94.	Tenofovir Alafenamide Fumarate
95.	Tenofovir Disproxil Fumarate
96.	Terbenafine HCl
97.	Tazarotene
98.	Tetracaine
99.	Tretinoin
100.	Velpatasvir
101.	Venlafaxine HCl
102.	Vitamin E
103.	Cinitapride Hydrogen Tartrate
104.	Cyclosporine
105.	Diclofenac Potassium
106.	Diclofenac Sodium
107.	Itopride
108.	Iron III Hydroxide Poly Maltose
109.	Rifaximin

ANNEXURE-H

MATERIAL SAFETY DATA SHEET

MATERIAL SAFETY DATA SHEET

Fusidic Acid (6990-06-3)



【Product Name】

Fusidic Acid

【Synonyms】

ent-(17Z)-16 α -(Acetyloxy)-3 β ,11 β -dihydroxy-4 β ,8,14-trimethyl-18-nor-5 β ,10 α -cholesta-17
(20),24-dien-21-oic acid hemihydrate.

【CAS】

6990-06-3

【Formula】

$C_{31}H_{48}O_6 \cdot \frac{1}{2}H_2O$

【Molecular Weight】

525.7

Physical and Chemical Properties

【Appearance】

White or almost white, crystalline powder.



JOYANG LABORATORIES

Haidu North Road, Sheyang Economic Development
Zone Yancheng, Jiangsu, 224300 CHINA
Tel: +86 515 88319898 Fax: +86 515 88319595
[Http://www.world-biopharm.com](http://www.world-biopharm.com)

【Solubility】

Practically insoluble in water; freely soluble in ethanol (96 per cent).

【pH】

4.77 – 4.82

【Melting Point】

178 °C- 193 °C

First Aid Measures

【Ingestion】

If swallowed, wash out mouth with water provided person is conscious. Call a physician.

【Inhalation】

If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

【Skin】

In case of skin contact, flush with copious amounts of water for at least 15 minutes.
Remove contaminated clothing and shoes. Call a physician.

【Eyes】

In case of contact with eyes, flush with copious amounts of water for at least 15 minutes.
Assure adequate flushing by separating the eyelids with fingers. Call a physician.

Handling and Storage

【Storage】

Protected from light, at a temperature of 2 °C to 8 °C

Hazards Identification

【Inhalation】

May be harmful if inhaled.

【Ingestion】



JOYANG LABORATORIES

Haidu North Road, Sheyang Economic Development
Zone Yancheng, Jiangsu, 224300 CHINA.
Tel: +86 515 88319898 Fax: +86 515 88319595
[Http://www.world-biopharm.com](http://www.world-biopharm.com)

Harmful if swallowed.

Exposure Controls/Personal Protection

【Personal Protection】

Wear appropriate government approved respirator, chemical-resistant gloves, safety goggles, other protective clothing.

【Exposure Effects】

Harmful. Harmful if swallowed.

Fire Fighting Measures

Extinguish using Water spray, Carbon dioxide, dry chemical powder, or appropriate foam.

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Accidental Release Measures

Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

Stability

Stable at normal temperatures and pressures.

Date:2014/1/15

Signature:

zhao Jianyun

SAFETY DATA SHEET

HALOBETASOL PROPIONATE

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
1.1 Product Identifier	
Substance Name	Halobetasol Propionate
CAS-No.	66852-54-8
EC-No.	686-247-0
Chemical Name	21-chloro-6 α ,9-difluoro-11 β ,17-dihydroxy-16 β -methylpregna-1,4-diene-3,20-dione, 17-propionate
Synonyms	*Ultrate, *Ulobetasol propionate
Formula	C ₂₅ H ₃₁ ClF ₂ O ₅
Molecular Weight	484.96 g/mol
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Identified uses	Laboratory chemicals, Manufacture of substances
1.3 Details of supplier of safety data sheet	
Company	Symbiotica Specialty Ingredients Sdn. Bhd.
Address	13, Lorong Perusahaan Sungai Lokan 2, Taman Industri Sungai Lokan, 13800, Butterworth, Pulau Pinang, Malaysia
Telephone	+604-5189000
Fax	+604-3581700
E-mail address	symbioti@symbiotica.com.my
1.4 Emergency telephone number	
Emergency Phone	+604-5189000

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Reproductive Toxicity	Category 2
Specific Target Organ Toxicity (Repeated Exposure)	Category 1
2.2 Label elements	
Labeling according to Regulation (EC) No 1272/2008 (CLP)	
Hazard pictograms:	
GHS07: Exclamation Mark	GHS08: Health Hazard
	

Signal Word	Danger
Hazard Statements	
H361	Suspected of damaging fertility or the unborn child
H372	Causes damage to organs (endocrine system) through prolonged or repeated exposure
Precautionary Statements	
P203	Obtain, read and follow all safety instructions before use.
P260	Do not breathe dust/fumes/gases/mist/vapour/sprays.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection as required.
P319	Get medical help if you feel unwell
Other hazards	
None.	

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Name	CAS Number	Quantity
Halobetasol Propionate	66852-54-8	100%

3.2 Mixtures

Not applicable.

SECTION 4: FIRST-AID MEASURES

4.1 Description of first aid measures

If Inhaled	May cause irritation. Remove to fresh air.
In Case of Skin Contact	May cause irritation. Wash with plenty of water. Corticosteroids can be absorbed through the skin and may cause systemic effects.
In Case of Eye Contact	May cause irritation. Flush with copious quantities of water.
If Ingested	May cause irritation. Flush out mouth with water.

4.2 Most Important Symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2).

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active pharmaceutical agent.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher
Unsuitable extinguishing media	Do not use a heavy water stream.

5.2 Special Hazards arising from the substance or mixture

Vapour	May emit irritant fumes during combustion.

5.3 Advice for firefighters

Special protective equipment for fire-fighters	Wear self-contained breathing apparatus for firefighting if necessary

SECTION 6: ACCIDENTAL RELEASE MEASURES	
General	Remove ignition sources. Evacuate area.
6.1 Personal precautions, protective equipment and emergency procedures	
Wear approved respiratory protection, chemically compatible gloves and protective clothing.	
6.2 Environment precautions	
Try to prevent further leakage or spillage. Keep the product away from drains or water courses.	
6.3 Methods and materials for containment and cleaning up	
Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal.	
6.4 Reference to other sections	
For disposal, refer section 13.	

SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Avoid all contact and inhalation of dust, mists and/or vapors associate with the material. Wash thoroughly after handling.	
7.2 Conditions for safe storage, including any incompatibilities	
Store in between 2°C to 8°C place. Keep container tightly closed in a dry and well-ventilated place.	
7.3 Specific end uses	
No data available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 Control parameters	
No data available	
8.2 Exposure controls	
Appropriate engineering control	Keep in a well-ventilated room. Use only in an exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).
Personal Protective Equipment	
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place.
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pair of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing the other personal protective equipment.
Skin and body protection	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Eye protection	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection is preferred. Maintain eyewash facilities in the work area.
Hygiene measures	Provide local exhaust or general room ventilation. Apply general industrial hygiene measures

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Solid
Colour	White or almost white
Appearance	Powder
Solubility	Acetone – Soluble Methanol – Sparingly soluble

9.2 Other safety information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	Stable under normal conditions.
10.2 Chemical Stability	Stable
10.3 Possibility of hazardous reactions	None under normal conditions.
10.4 Conditions to avoid	No data available.
10.5 Incompatible materials	Acids, Bases, Oxidizing agents and reducing agents.
10.6 Hazardous decomposition products	Toxic fumes of fluoride or chloride if heated to decomposition.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity	No data available.
Carcinogenicity	No data available.
Chronic exposure	No data available.
Additional Information	RTECS: No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	General: Hazardous waste: Use suitable disposal containers.
12.2 Persistence and degradability	No data available.
12.3 Bioaccumulative potential	No data available.
12.4 Mobility in soil	No data available.
12.5 PBT & vPvB assessment	No data available.
12.6 Endocrine disrupting effects	No data available.
12.7 Other adverse effects	No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product	Dispose this material at hazardous or special waste collection point. Dispose in a safe manner in accordance with the local/national regulations.
Contaminated packaging	Dispose of as unused product.
Special precautions	Avoid release to the environment as it has hazardous components.

SECTION 14: TRANSPORTATION

14.1 UN Number	No data available.
14.2 UN proper shipping name	
ADR/RID	Not dangerous goods.

IMDG	Not dangerous goods.
IATA	Not dangerous goods.
14.3 Transport hazard class(es)	Not applicable
14.4 Packaging group	Not applicable
14.5 Environmental hazards	No hazard identified
14.6 Special precaution for user	No data available

SECTION 15: REGULATORY INFORMATION

Labeling according to EC Directives

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available

15.2 Chemical safety assessment

No data available

SECTION 16: OTHER INFORMATION

Indication of changes: all the sections are updated according to ECHA Guidance

Abbreviations and acronyms:

a.	CAS NO	:	Chemical abstracts service number
b.	EC	:	European Commission
c.	CLP	:	Classification Labelling And Packaging Regulation
d.	STOT	:	Specific target organ toxicity
e.	LD50	:	Lethal dose
f.	RTECS	:	Registry of Toxic Effects of Chemical Substances
g.	ECHA	:	European Chemicals Agency
h.	PBT	:	Persistent, Bioaccumulative and Toxic
i.	vPvB	:	very Persistent and very Bioaccumulative

Additional information:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the mentioned product, storage, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other product or in the case of processing, the information the material safety data sheet is not necessarily valid for the new made-up material.



RAKSHIT PHARMACEUTICALS LIMITED

Plot No 68/A, JN Pharma City, Parawada, Vizag - 531021, AP, India.

MATERIAL SAFETY DATA SHEET
PRODUCT : AZATHIOPRINE BP

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE
COMPANY/UNDERTAKING**

1.1. Product identifier

Trade name: Azathioprine

CAS-number: 446-86-6

Reach registration number: NA

1.2. Relevant identified uses of the substance or mixture and uses advised against

The uses of the chemical: Active pharmaceutical ingredients

Classification of the economic activities (NACE): 212

Use categories (UC62): 41

1.3. Details of the supplier of the safety data sheet:

Manufacturer : Rakshit Pharmaceuticals Limited

Street address: Plot No : 68/A, J.N.Pharma City, Parawada, Visakhapatnam, A.P, India.

Telephone number: 08924-236075

E-mail address: headqa@rakshitpharma.com

1.4. Emergency telephone number : 08924-236075

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to regulation EC 1272/2008 Acute Tox. 4 H302,

Carc. 1B H350,

Muta. 1B H340,

Repr. 2 H361d,

Eye Irrit. 2 H319,

STOT SE 3 H335,

Skin Irrit. 2 H315,

H Statements Harmful if swallowed.

May cause cancer. May cause genetic defects. Suspected of damaging the unborn child. Causes serious eye irritation. May cause respiratory irritation. Causes skin irritation.



RAKSHIT PHARMACEUTICALS LIMITED

Plot No 68/A, JN Pharma City, Parawada, Vizag - 531021, AP, India.

MATERIAL SAFETY DATA SHEET
PRODUCT : AZATHIOPRINE BP

2.2. Label elements

Hazard Pictograms



Signal word



Danger

H Statements

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H340 May cause genetic defects.

H350 May cause cancer.

H361d Suspected of damaging the unborn child.

P Statements

P308+P313 IF exposed or concerned: Get medical advice/attention.

P302+P352 IF ON SKIN: Wash with soap and water.

P305+P351+P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do, continue rinsing.

P280 Wear protective gloves/protective clothing/eye protection.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P501 Dispose of contents according to national and local law.

2.3. Other hazards

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances



RAKSHIT PHARMACEUTICALS LIMITED

Plot No 68/A, JN Pharma City, Parawada, Vizag - 531021, AP, India.

MATERIAL SAFETY DATA SHEET

PRODUCT : AZATHIOPRINE BP

Name of the ingredient : Azathioprine

CAS-number : 446-86-6

EC-number : 207 - 175 - 4

Registration number : NA

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions Helpers should ensure their own protection.

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing.

If appropriate, give artificial respiration or oxygen. If appropriate, give oxygen. Get medical advice/attention.

Skin contact Remove/Take off immediately all contaminated clothing.

IF ON SKIN: Wash with soap and water.

If skin irritation occurs: Get medical advice/attention.

Eye contact IF IN EYES: Rinse continuously with water for several minutes. Get medical advice / attention.

Ingestion Do NOT induce vomiting. Rinse mouth.

If the patient is conscious, give plenty of water (2 - 4 glasses). Get medical advice/attention.

4.2. Most important symptoms and effects, both acute and delayed

See section 11 for symptoms of exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media Foam, Water , Powder, Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters : Isolating breathing apparatus eg. compressed



RAKSHIT PHARMACEUTICALS LIMITED

Plot No 68/A, JN Pharma City, Parawada, Vizag - 531021, AP, India.

MATERIAL SAFETY DATA SHEET
PRODUCT : AZATHIOPRINE BP

breathing apparatus and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.

6.2. Environmental precautions :

Data not available.

6.3. Methods and material for containment and cleaning up

Collect spilled powder without dusting into tight closed container.

6.4. Reference to other sections

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in well-ventilated space. Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

Keep cool. Store in a dry place. Keep container tightly closed. Protect from moisture. Protect from sunlight. See incompatible materials in section 10.5.

7.3. Specific end use(s)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure controls

Appropriate engineering controls

Handle in well-ventilated space. All exposure must be avoided.

Respiratory protection

In dust making work use respirator, filtration P3. In laboratories work in fume hood or under dust control hood. See particular department's regulations of protection.

Hand protection

Use protective gloves (e.g. nitrile or neopren gloves).

Eye protection

Use protective goggles.



RAKSHIT PHARMACEUTICALS LIMITED

Plot No 68/A, JN Pharma City, Parawada, Vizag - 531021, AP, India.

MATERIAL SAFETY DATA SHEET
PRODUCT : AZATHIOPRINE BP

Skin protection

Wear protective clothing.

Environmental exposure controls

Releases to the environment should be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state : Crystalline

Colour : Nearly white

Odour : Odourless

9.1. Information on basic physical and chemical properties

pH Value : 6 - 7

Melting point : 224 °C

Water solubility : Insoluble

SECTION 10: STABILITY AND REACTIVITY

10.1. Conditions to avoid : Moisture, Light.

10.2. Incompatible materials : Strong oxidants

10.3 Hazardous decomposition products

May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed. LD50 = 600 mg/kg (rat, oral)

Skin irritation and corrosion : Causes skin irritation.

Skin sensitization : Data not available.

Serious eye damage and irritation : Causes serious eye irritation.

Respiratory irritation : May cause respiratory irritation.

Respiratory sensitization : Data not available.

Carcinogenicity : May cause cancer. The substance has been found carcinogenic in animal tests.

Germ cell mutagenicity : May cause genetic defects. Substance has been found mutagenic in animal



RAKSHIT PHARMACEUTICALS LIMITED

Plot No 68/A, JN Pharma City, Parawada, Vizag - 531021, AP, India.

MATERIAL SAFETY DATA SHEET PRODUCT : AZATHIOPRINE BP

tests.

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Long term or frequent contact may cause irritation.

Aspiration hazard : Data not available.

Repeated dose toxicity : Data not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

12.1. Persistence and degradability

Not readily biodegradable.

12.2. Bioaccumulative potential

Octanol-water partition coefficient(KOW) Data not available.

Bioconcentration factor : Data not available.

12.2. Mobility in soil : Data not available.

12.5. Results of PBT and vPvB assessment : Data not available.

12.6. Other adverse effects : Data not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

SECTION 14: TRANSPORT INFORMATION

14.1. Transport hazard class(es) (ADR/RID, IMDG, ICAO/IATA)

This product is not regulated under the transport regulations.

14.2. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for substance or mixture

The product has not been fully tested.

**RAKSHIT PHARMACEUTICALS LIMITED**

Plot No 68/A, JN Pharma City, Parawada, Vizag - 531021, AP, India.

MATERIAL SAFETY DATA SHEET**PRODUCT : AZATHIOPRINE BP**

15.2. Chemical Safety Assessment : No

SECTION 16: OTHER INFORMATION**Further information**

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Rakshit Pharmaceuticals Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the Safety Data Sheet

Information provided by the supplier

Information which has been added, deleted or revised

Updated section / sections:



CLOBETASOL PROPIONATE

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product Identifier

Substance Name Clobetasol Propionate

CAS-No 25122-46-7

EC-No. 246-634-3

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified Uses Laboratory chemicals, Manufacture of substances

1.3 Details of supplier of safety data sheet

Company Symbiotica Speciality Ingredients Sdn. Bhd.

Address 13, Lorong Perusahaan Sungai Lokan 2, Taman Industri Sungai Lokan, 13800, Butterworth, Pulau Pinang, Malaysia

Telephone +604-5189000

Fax +604-3581700

E-mail Address symbioti@symbiotica.com.my

1.4 Emergency telephone number

Emergency Phone +604-5189000

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Repr. 1B, STOT RE 2, Aquatic Chronic 4

2.2 Label elements

Classification according to Regulation (EC) No 1272/2008 (CLP)

Hazard pictograms: GHS08: Health hazard



Signal Word

Danger

Hazards statement (s)

H360 May damage fertility or the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

H413 May cause long lasting harmful effects to aquatic life.

Precautionary statement (s)

P260 : Do not breathe dust.

P281 : Use personal protective equipment as required.

P314 : Get medical advice/attention if you feel unwell.

2.3 Other hazards

None

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Chemical Name 21-Chloro-9-fluoro-11 β ,17-dihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17-propionate

Synonyms	*Chlobesol, *Dermoval, *Dermovate, *Dermoxin, *Dermoxinale
Formula	$C_{25}H_{12}ClFO_5$
Molecular Weight	466.97 g/mol
Classification	Repr. 1B, STOT RE 2, Aquatic Chronic 4

4. FIRST AID MEASURES

4.1 Description of first aid measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
If Inhaled	Assure fresh air breathing. If you feel unwell, seek medical advice
In Case of Skin Contact	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
In Case of eye contact	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persists.
If Swallowed	Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.

4.2 Most important symptoms and effects, both acute and delayed

Symptom/effects after digestion: Symptoms may include dizziness, headache, nausea and loss of coordination.

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent. Pharmaceutical.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Water spray, carbon dioxide and dry powder. Use water spray or fog for cooling exposed containers.
Unsuitable extinguishing media	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Vapor	Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

5.3 Advice for firefighters

Special protective equipment for fire-fighters	Wear self contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

General	Remove ignition sources. Evacuate area.

6.1 Personal precautions, protective equipment and emergency procedures

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environment precautions

No data available

6.3 Methods and materials for containment and cleaning up

To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation.

6.4 Reference to other sections

For disposal refer section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in 15°C to 30°C place. Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)	
No data available	
8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 Control parameters	
No data available	
8.2 Exposure controls	
<i>Appropriate engineering control</i>	
Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).	
<i>Personal Protective Equipment</i>	
<i>Respiratory protection</i>	Wear approved mask (P3). In case of insufficient ventilation, wear suitable respiratory equipment.
<i>Hand protection</i>	Chemically resistant protective gloves.
<i>Eye protection</i>	Safety glasses.
<i>Skin and body protection</i>	Use chemically protective clothing.
<i>Hygiene measures</i>	Provide local exhaust or general room ventilation. General industrial hygiene measures.
9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
<i>Appearance</i>	White crystalline solid.
<i>Solubility</i>	Water – Practically insoluble Acetone – Freely Soluble Ethanol (96%) – Sparingly Soluble
9.2 Other safety information	
No data available	
10. STABILITY AND REACTIVITY	
10.1 Reactivity	
Stable under normal conditions.	
10.2 Chemical Stability	
Stable.	
10.3 Possibility of hazardous reactions	
No data available	
10.4 Conditions to avoid	
Heat, Direct sunlight.	
10.5 Incompatible materials	
No data available	
10.6 Hazardous decomposition products	
Carbon dioxide, Hydrogen fluoride, Chlorides, Carbon monoxide. When heated to decomposition, emits dangerous fumes.	
11. TOXICOLOGICAL INFORMATION	
11.1 Information on toxicological effects	
<i>Acute toxicity</i>	LD50 Oral - rat - > 3,000 mg/kg Exposure may produce an allergic reaction.
<i>Carcinogenicity</i>	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
<i>Additional Information</i>	RTECS: TU3725000

12. ECOLOGICAL INFORMATION	
12.1 Toxicity	General: Hazardous waste. Use suitable disposal containers.
12.2 Persistence and degradability	No data available
12.3 Bioaccumulative potential	No data available
12.4 Mobility in Soil	No data available
12.5 PBT and vPvB assessment	No data available
12.6 Other adverse effects	Log P octanol / water at 20°C : 3.49

13. DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
<i>Product</i>	Observe all federal, state and local environmental regulations.
<i>Contaminated packaging</i>	Dispose container at hazardous or special waste collection point.
<i>Special precautions</i>	Avoid release to the environment as it has hazardous components.

14. TRANSPORTATION	
14.1 UN number	No data available
14.2 UN proper shipping name	
<i>ADR/RID</i>	Not dangerous goods.
<i>IMDG</i>	Not dangerous goods.
<i>IATA</i>	Not dangerous goods.
14.3 Transport Hazard Class(es)	Not applicable
14.4 Packaging group	Not applicable
14.5 Environmental hazards	No hazard identified
14.6 Special precaution for user	No data available

15. REGULATORY INFORMATION	
Labeling according to EC Directives.	
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	No data available
15.2 Chemical safety assessment	No data available

16. OTHER INFORMATION	
Indication of changes: All the sections are updated according to ECHA Guidance	
Abbreviations and acronyms:	
a. CAS NO	: Chemical abstracts service number
b. EC	: European Commission
c. CLP	: Classification Labelling And Packaging Regulation
d. STOT	: Specific target organ toxicity
e. LD50	: Lethal dose
f. RTECS	: Registry of Toxic Effects of Chemical Substances
g. ECHA	: European Chemicals Agency
h. PBT	: Persistent, Bioaccumulative and Toxic
i. vPvB	: very Persistent and very Bioaccumulative
Additional information:	
The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the mentioned product, storage, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other product or in the case of processing, the information the material safety data sheet is not necessarily valid for the new made-up material.	

SAFETY DATA SHEET

HYDROCORTISONE ACETATE

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
1.1 Product Identifier	
Substance Name	Hydrocortisone Acetate
CAS-No.	50-03-3
EC-No.	200-004-4
Chemical Name	Hydrocortisone Acetate
Synonyms	Hydrocortisone 21-acetate, Cortisol 21-acetate
Formula	$C_{23}H_{36}O_6$
Molecular Weight	404.5 g/mol
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Identified uses	Manufacture of substances
1.3 Details of supplier of safety data sheet	
Company	Symbiotica Specialty Ingredients Sdn. Bhd.
Address	13, Lorong Perusahaan Sungai Lokan 2, Taman Industri Sungai Lokan, 13800, Butterworth, Pulau Pinang, Malaysia
Telephone	+604-5189000
Fax	+604-3581700
E-mail address	symbioti@symbiotica.com.my
1.4 Emergency telephone number	
Emergency Phone	+604-5189000

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Reproductive Toxicity	Category 1B
Specific Target Organ Toxicity (Repeated exposure)	Category 2
2.2 Label elements	
Labeling according to Regulation (EC) No 1272/2008 (CLP)	
Hazard pictograms:	
GHS08: Health Hazard	
	

Signal Word	Warning
Hazard Statements	
H360Df	May damage the unborn child. Suspected of damaging fertility.
H373	Causes damage to organs through prolonged or repeated exposure.
Precautionary Statements	
P203	Obtain, read and follow all safety instructions before use.
P260	Do not breathe dust/fumes/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

P318	If exposed or concerned, get medical advice.
P319	Get medical help if you feel unwell.
P405	Store locked up.
Other hazards	
None.	

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Name	CAS Number	Quantity
Hydrocortisone Acetate	50-03-3	100%

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

If Inhaled	Remove to fresh air. If breathing becomes difficult, call a physician.
In Case of Skin Contact	Flush with copious amounts of water and soap for at least 15 minutes. Remove contaminated clothing and shoes.
In Case of Eye Contact	Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes.
If Ingested	Wash out mouth with water and administer fresh water provided that the person is conscious.

4.2 Most Important Symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active pharmaceutical agent.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None.

5.2 Special Hazards arising from the substance or mixture

Vapour	Development of hazardous combustion gases or vapours are possible in the event of fire.

5.3 Advice for firefighters

Special protective equipment for fire-fighters	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Emits toxic fumes under fire conditions. Risk of dust explosion cannot be excluded.

SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
Switch off electrical equipment and any other sources of ignition. Evacuate area. Wear self-contained breathing apparatus, appropriate boots and heavy rubber gloves. Avoid raising dust/mist.	
6.2 Environment precautions	
Do not let product enter sewers.	
6.3 Methods and materials for containment and cleaning up	
Collect residues manually, by wiping with small quantity of detergent solution, place in a bag and hold for waste disposal. Ventilate area and wash spill site with water/detergent solution after material pick up is complete.	
6.4 Reference to other sections	
For disposal, refer to section 13.	

SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Avoid use with incompatible materials.	
7.2 Conditions for safe storage, including any incompatibilities	
Store in 15°C to 30°C place. Keep unopened and tightly closed in the original container protected from incompatible materials, heat, direct sunlight and sources of ignition.	
7.3 Specific end uses	
No data available.	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 Control parameters	
No data available.	
8.2 Exposure controls	
Appropriate engineering control	Keep in a well-ventilated room. Use only in an exhaust booth with integrated high efficiency particulate air (HEPA) filter.
Personal Protective Equipment	
Respiratory protection	Wear a protecting mask (P3 filter).
Hand protection	Wear compatible chemical-resistant gloves. The protective gloves to be used must comply with specifications of EC Directive 89/686/EEC and the related standard EN374.
Skin and body protection	Wear chemically protective clothing.
Eye protection	Wear protective chemical safety glasses with side shields.
Hygiene measures	Provide local exhaust or general room ventilation. General industrial hygiene measures.
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
Physical state	Solid.
Colour	White or almost white.
Appearance	Crystalline powder.
Solubility	Water – Practically insoluble Ethanol – Slightly soluble

	Methylene Chloride – Slightly soluble Dioxane – Soluble
9.2 Other safety information	
No data available.	

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	Stable under normal conditions.
10.2 Chemical Stability	Stable.
10.3 Possibility of hazardous reactions	No data available.
10.4 Conditions to avoid	Heat and ignition sources.
10.5 Incompatible materials	Strong oxidizing agents.
10.6 Hazardous decomposition products	Carbon oxides and other substances may be produced in case of incomplete decomposition. Hazardous polymerization will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
Acute toxicity	LD ₅₀ (Oral-rat): 5000 mg/kg LD ₅₀ (Skin-rat): 5 mg/kg LD ₅₀ (Inhalation-rat): 0.62 mg/m ³ /4h Remarks: Nutritional and Gross Metabolic: Weight loss or decreased weight gain.
Carcinogenicity	Long term studies in animal (rats, rabbits, and mice) showed no evidence of carcinogenicity attributable to oral administration of corticosteroids.
Potential health effects	Hydrocortisone is a naturally secreted and pharmacologically potent substance. It is readily absorbed through the skin and rapidly eliminated in the urine. Harmful: Danger of serious damage to health by prolonged exposure through inhalation and in contact with skin and if swallowed. May cause skin damage, psychic disturbances, adrenal suppression, immune system depression, irregular heartbeat and high blood pressure. Possible risk of impaired fertility. Possible of risk of harm to the unborn child.
Signs and Symptoms of Exposure	Risk of carcinogenicity, mutagenicity, sensitization and narcosis cannot be excluded.
Additional Information	RTECS: GM8960000

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	General: Hazardous waste. Use suitable disposal containers.
12.2 Persistence and degradability	Minimally biodegradable.
12.3 Bioaccumulative potential	No data available.
12.4 Mobility in soil	No data available.
12.5 PBT & vPvB assessment	No data available.
12.6 Endocrine disrupting effects	No data available.
12.7 Other adverse effects	No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product	Dispose in a safe manner in accordance with the local/national regulations.
Contaminated packaging	Dispose its container at hazardous or special waste collection point.

SECTION 14: TRANSPORTATION

14.1 UN Number	No data available.
14.2 UN proper shipping name	
ADR/RID	Not dangerous goods.
IMDG	Not dangerous goods.
IATA	Not dangerous goods.
14.3 Transport hazard class(es)	Not applicable.
14.4 Packaging group	Not applicable.
14.5 Environmental hazards	No hazard identified.
14.6 Special precaution for user	No data available.

SECTION 15: REGULATORY INFORMATION

Labelling according to EC Directives

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available.

15.2 Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

Indication of changes: all the sections are updated according to ECHA Guidance

Abbreviations and acronyms:

a.	CAS NO	:	Chemical abstracts service number
b.	EC	:	European Commission
c.	CLP	:	Classification Labelling And Packaging Regulation
d.	STOT	:	Specific target organ toxicity
e.	LD50	:	Lethal dose
f.	RTECS	:	Registry of Toxic Effects of Chemical Substances
g.	ECHA	:	European Chemicals Agency
h.	PBT	:	Persistent, Bioaccumulative and Toxic
i.	vPvB	:	very Persistent and very Bioaccumulative

Additional information:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the mentioned product, storage, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other product or in the case of processing, the information the material safety data sheet is not necessarily valid for the new made-up material.



BETAMETHASONE DIPROPIONATE

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING	
1.1 Product Identifier	
Substance Name	Betamethasone Dipropionate
CAS-No	5593-20-4
EC-No.	227-005-2
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Identified Uses	Laboratory chemicals, Manufacture of substances
1.3 Details of supplier of safety data sheet	
Company	Symbiotica Speciality Ingredients Sdn. Bhd.
Address	13, Lorong Perusahaan Sungai Lokan 2, Taman Industri Sungai Lokan, 13800, Butterworth, Pulau Pinang, Malaysia.
Telephone	+604-5189000
Fax	+604-3581700
E-mail Address	symbioti@symbiotica.com.my
1.4 Emergency telephone number	
Emergency Phone	+604-5189000

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008 (CLP)
Repr. 1B & STOT RE 2

2.2 Label elements
Classification according to Regulation (EC) No 1272/2008 (CLP)
Hazard pictograms: GHS08: Health hazard



Signal Word
Warning

Hazards statement (s)
H360D: May damage the unborn child.
H373: Causes damage to organs.

Precautionary statement (s)
P260 : Do not breathe dust.
P281 : Use personal protective equipment as required.
P314 : Get medical advice/attention if you feel unwell.

2.3 Other hazards
None

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances	
Chemical Name	9 α -Fluoro-16 β -Methyl-11 β ,17 α ,21-trihydroxy-1,4-pregnadiene-3,20-dione 17,21-dipropionate
Synonyms	*Betamethasone dipropionate, *Betamethasone 17,21-dipropionate, *Diproderm.

	*Diprolene, *Diprosis, *Diprosone, *S-3440
<i>Formula</i>	$C_{26}H_{37}FO_7$
<i>Molecular Weight</i>	504.59 g/mol
<i>Classification</i>	Repr.1B; H360D, STOT RE 2;H373

4. FIRST AID MEASURES

4.1 Description of first aid measures

<i>General Advice</i>	Consult a physician. Show this safety data sheet to the doctor in attendance.
<i>If Inhaled</i>	Assure fresh air breathing. If you feel unwell, seek medical advice.
<i>In Case of Skin Contact</i>	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
<i>In Case of eye contact</i>	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persists.
<i>If Swallowed</i>	Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after ingestion: Symptoms may include dizziness, headache, nausea and loss of coordination.

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent. Pharmaceutical.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

<i>Suitable extinguishing media</i>	Water spray, carbon dioxide and dry powder.
<i>Unsuitable extinguishing media</i>	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

<i>Vapor</i>	Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

5.3 Advice for firefighters

<i>Special protective equipment for fire-fighters</i>	Wear self contained breathing apparatus for fire fighting if necessary. Avoid (reject) fire-fighting water to enter environment. Prevent entry to sewers and public waters.

6. ACCIDENTAL RELEASE MEASURES

<i>General</i>	Remove ignition sources. Evacuate area.

6.1 Personal precautions, protective equipment and emergency procedures

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environment precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3 Methods and materials for containment and cleaning up

Clean spills promptly. To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation.

6.4 Reference to other sections

For disposal refer section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in 15°C to 30°C place. Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**8.1 Control parameters**

No data available

8.2 Exposure controls*Appropriate engineering control*

Keep in a well-ventilated room. Use only in an exhaust booth with integrated air filter, High efficiency particulate air filter (HEPA filter).

Personal Protective Equipment

<i>Respiratory protection</i>	Wear approved mask (P3). In case of insufficient ventilation, wear suitable respiratory equipment.

<i>Hand protection</i>	Chemically resistant protective gloves.

<i>Eye protection</i>	Chemical goggles or safety glasses.

<i>Skin and body protection</i>	Use chemically protective clothing.

<i>Hygiene measures</i>	Provide local exhaust or general room ventilation. Material should be handled in a laboratory hood whenever possible.

9. PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

<i>Appearance</i>	White to almost white crystalline powder

<i>Melting Point</i>	Around 170 °C – 179 °C

<i>Solubility</i>	Water – Practically insoluble Acetone – Freely soluble Methylene chloride – Freely soluble Ethanol (96%) - Sparingly Soluble

9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY**10.1 Reactivity**

Stable under normal conditions.

10.2 Chemical Stability

Stable.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Heat, Direct sunlight.

10.5 Incompatible materials

Strong oxidizers.

10.6 Hazardous decomposition products

Carbon dioxide, Hydrogen fluoride, Carbon monoxide, Chlorides, When heated to decomposition, emits dangerous fumes.

11. TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects**

<i>Acute toxicity</i>	LD50 Oral – rat - > 4,000 mg/kg Endocrine disorders. May produce irregular heart beat and nervous symptoms. Oedema, Gastrointestinal disorders.

<i>Carcinogenicity</i>	No data Available

<i>Chronic toxicity</i>	Immune system suppression

<i>Reproductive toxicity</i>	Category 3: Substances which cause concern for humans owing to possible developmental toxic effects.
<i>Additional Information</i>	RTECS: TU4058000

12. ECOLOGICAL INFORMATION	
12.1 Toxicity	General: Hazardous waste. Use suitable disposal containers.
12.2 Persistence and degradability	Minimally biodegradable.
12.3 Bioaccumulative potential	No data available
12.4 Mobility in Soil	No data available
12.5 PBT and vPvB assessment	No data available
12.6 Other adverse effects	EC50-48 Hour-Daphnia magna [mg/L]: 1.9 Log P octanol / water at 20°C: 4.07

13. DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
<i>Product</i>	Observe all federal, state and local environmental regulations. This product contains hazardous components for the environment. Avoid release to the environment.
<i>Contaminated packaging</i>	Dispose its container at hazardous or special waste collection point.

14. TRANSPORTATION	
14.1 UN number	No data available
14.2 UN proper shipping name	
<i>ADR/RID</i>	Not dangerous goods.
<i>IMDG</i>	Not dangerous goods.
<i>IATA</i>	Not dangerous goods.
14.3 Transport Hazard Class(es)	Not applicable
14.4 Packaging group	Not applicable
14.5 Environmental hazards	No hazard identified
14.6 Special precaution for user	No data available

15. REGULATORY INFORMATION	
Labeling according to EC Directives.	
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
No data available	
15.2 Chemical safety assessment	
No data available	

16. OTHER INFORMATION	
Indication of changes: all the sections are updated according to ECHA Guidance	
Abbreviations and acronyms:	
a. CAS NO	: Chemical abstracts service number
b. EC	: European Commission
c. CLP	: Classification Labelling And Packaging Regulation
d. STOT	: Specific target organ toxicity
e. LD50	: Lethal dose
f. RTECS	: Registry of Toxic Effects of Chemical Substances
g. ECHA	: European Chemicals Agency
h. PBT	: Persistent, Bioaccumulative and Toxic
i. vPvB	: very Persistent and very Bioaccumulative

Additional information:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the mentioned product, storage, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other product or in the case of processing, the information the material safety data sheet is not necessarily valid for the new made-up material.

MATERIAL SAFETY DATA SHEET

Date: April 2, 2021

1. IDENTIFICATION

Product identification

Common Name Levofloxacin hemihydrate
Chemical name (-)-(S)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid hemihydrate

Manufacturer/ Importer/Supplier/Distributor information

Company name SHANGYU JINGXIN PHARMACEUTICAL CO., LTD.
Address No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and Technological Development Area, Zhejiang Province, P. R. China-312369
Phone +86-575-82728326
Fax: +86-575-82728551

2. HAZARD IDENTIFICATION

Physical hazards Not classified.
Health hazards Acute toxicity, oral Category 4
Specific target organ toxicity Single exposure Category 3 narcotic effects
OSHA hazard(s) Not classified.
Environmental hazards Not classified.
Label elements



Signal word Warning
Hazard statement Harmful if swallowed.
Precautionary statement
Prevention Wash thoroughly after handling.
Response Rinse mouth. If swallowed: Call a poison center/doctor if you feel unwell.
Storage Store tightly and protected from light.
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified(HNOC) Not classified.
Other hazards which do not result in classification None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance			
Chemical name	Common name and synonyms	CAS number	%
Levofloxacin hemihydrate	(S)-(-)-Ofloxacin	138199-71-0	100

4. FIRST-AID MEASURES

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. If skin irritation occurs: Get medical advice/attention.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
Most important symptoms /effects, acute and delayed	Central nervous system effects. Gastrointestinal disturbances.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Administer activated charcoal as slurry. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, administer phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For moderate or severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against <i>Clostridium difficile</i> colitis. Hemodialysis is unlikely to be of benefit, Peritoneal dialysis is not effective.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	Foam. Dry chemical or CO ₂ . Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment	Wear suitable protective equipment.

and precautions for firefighters

Fire-fighting equipment/ instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

7. HANDLING AND STORAGE

Precautions for safe handling

As a general rule, when handling the material, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Conditions for safe storage, including any incompatibilities

Store in tight, light-resistant container. This material should be handled and stored per label instructions to ensure product integrity.

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of

engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact.

Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Light yellowish-white to yellow-white crystals or crystalline powder
Physical state	Solid.
Form	Powder.
Odor	Odorless
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	435.2 - 444.2 °F (224 - 229°C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	

Flammability limit - lower	Not available. (%)
Flammability limit - upper	Not available. (%)
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Very soluble.
Partition coefficient(n-octanol/water)	-0.52.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Fluoroquinolone.
Molecular formula	C ₁₈ H ₂₀ FN ₃ O ₄
Molecular weight	370.38
Solubility (other)	Soluble in dimethylsulfoxide and in acetic acid; sparingly soluble in water, in acetone, and in methanol; practically insoluble in glycerin and in n-octanol.

10. STABILITY AND REACTIVITY

Reactivity	None known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Contact with incompatible materials.
Hazardous decomposition products	Oxidizing agents.

11. TOXICOLOGICAL PROPERTIES

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Classification not possible.
Skin contact	Classification not possible.
Eye contact	Classification not possible.
Permitted Daily Exposure	330µg/day
Symptoms related to the physical, chemical, and toxicological characteristics	Fluoroquinolones: Nausea, Vomiting, Diarrhea, Altered taste, Dizziness, Drowsiness, Headache, Sleep disturbances, Slurred speech, Tremors, Restlessness, Convulsions, Skin rash, Joint tenderness or swelling, numbness or tingling of hands or feet, Swelling.

Delayed and immediate effects of exposure	Fluoroquinolones: Tendon rupture, Tendonitis, Superinfection, Heart arrhythmias, Rhabdomyolysis, Liver damage, Central nervous system stimulation, Photosensitivity, Peripheral neuropathy.
Cross sensitivity	Persons sensitive to one fluoroquinolone or to chemically related quinolone derivatives (cinoxacin, nalidixic acid) may be sensitive to this material also.
Medical conditions aggravated by exposure	Fluoroquinolones: Myasthenia gravis, History of tendonitis or tendon rupture, Bradycardia, QTc-interval prolongation, Hypokalemia or hypomagnesemia, Impaired liver or kidney function. History of seizures, Central nervous system disorders, Blood disorders, Photosensitivity disorders.

Acute toxicity

Product	Species	Test Results
Levofloxacin hemihydrate (CAS 138199-71-0)		
Oral		
LD50	Mouse	1803 mg/kg
	Rat	1478 mg/kg

Skin corrosion/irritation	Classification not possible.
Serious eye damage/eye irritation	Not classified.
Local effects	100 µL/kg Eye irritation test Result: Non-irritant. Species: Rabbit

Respiratory or skin sensitization	
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Not classified.
Sensitization	Not classified.
Germ cell mutagenicity	Not classified.
Mutagenicity	Ames test Result: Negative. Chinese hamster ovary mutation assay Result: Negative. In vitro chromosomal aberration assay Result: Positive. In vitro sister chromatid exchange assay Result: Positive. Mouse dominant lethal assay Result: Negative. Mouse micronucleus test Result: Negative. Not classified. This product is not considered to be a carcinogen by IARC.
Carcinogenicity	

	ACGIH, NTP, or OSHA.
	100 mg/kg/day Carcinogenicity test
	Result: Not carcinogenic.
	Species: Rat
	Test Duration: 2 years
	300 mg/kg/day Carcinogenicity test
	Result: Not carcinogenic.
	Species: Mouse
Reproductive toxicity	Not classified.
Reproductive	360 mg/kg/day Reproductivity test
	Result: No adverse effects on fertility.
	Species: Rat
	50 mg/kg/day Reproductivity test
	Result: No birth defects observed.
	Species: Rabbit
	810 mg/kg/day Reproductivity test
	Result: Fetotoxicity observed; reduction in fetal weight and delay in ossification.
	Species: Rat
	Test Duration: 2 years
Specific target organ toxicity - single exposure-	Classification not possible.
Specific target organ toxicity-repeated exposure-	Classification not possible.
Aspiration hazard	Not classified.

12. ECOLOGICAL INFORMATION

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	Not available.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. DISPOSAL CONSIDERATIONS

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. TRANSPORT INFORMATION

DOT

Not regulated as dangerous goods.

IATA

Not regulated as a dangerous good.

IMDG Code

Not regulated.

Transport in bulk according to
Annex II of MARPOL 73/78 and
the IBC Code

Not available.

General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. REGULATORY INFORMATION

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

Not listed.

SARA 302 Extremely hazardous
substance

SARA 311/312 Hazardous chemical

Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Safe Drinking Water Act(SDWA)

Not regulated.

Food and Drug Administration
(FDA)

Not regulated.

US state regulations

US. California Proposition 65

California Safe Drinking Water and Toxic

Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. OTHER INFORMATION

Issued date	April 2, 2021
Prepared by	SHANGYU JINGXIN PHARMACEUTICAL CO., LTD
Version No.	#6
Further information	Not available.
Disclaimer	The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.
Revision Information	This document has undergone change in term of compilation foundation.



METHYLPREDNISOLONE ACEPONATE

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product Identifier

Substance Name	Methylprednisolone Aceponate
CAS-No	86401-95-8
EC-No.	658-084-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified Uses	Laboratory chemicals, Manufacture of substances (corticosteroid)

1.3 Details of supplier of safety data sheet

Company	Symbiotica Speciality Ingredients Sdn. Bhd.
Address	13, Lorong Perusahaan Sungai Lokan 2, Taman Industri Sungai Lokan, 13800, Butterworth, Pulau Pinang, Malaysia
Telephone	+604-5189000
Fax	+604-3581700
E-mail Address	symbioti@symbiotica.com.my

1.4 Emergency telephone number

Emergency Phone	+604-5189000

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)	Reproductive toxicity (Category 1A)

2.2 Label elements

Classification according to Regulation (EC) No 1272/2008 (CLP)	Hazard pictograms: GHS08: Health hazard



Signal Word
Danger

Hazards statement (s)

H360 DF: May damage fertility or the unborn child

Precautionary statement (s)

P281: Use personal protective equipment as required.

2.3 Other hazards

None

3. Composition / Information on Ingredients

Chemical Name	Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11-hydroxy-6-methyl-17-(1-oxopropoxy)-6(alpha,11 beta) 21-Acetoxy-11beta-hydroxy-6alpha-methyl-17-propionyloxy-1,4-pregnadien-3,20-dion
Synonyms	* Advantan, * SH-440, * ZK 91588

Formula	$C_{17}H_{16}O_2$
Molecular Weight	472.63 g/mol
Classification	Repr. 1A; 360 Df

4. FIRST AID MEASURES

4.1 Description of first aid measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
If Inhaled	Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.
In Case of Skin Contact	Immediately flush eyes or skin with copious amount of water for at least 15 minutes while removing contaminated clothing and shoes.
In Case of eye contact	Immediately flush eyes or skin with copious amount of water for at least 15 minutes while removing contaminated clothing and shoes.
If Swallowed	Wash out mouth with water provided person is conscious. Give 2-4 cups of milk or water. Call a physician. Wash contaminated clothing before reuse.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after ingestion: Symptoms may include dizziness, headache, nausea and loss of coordination

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent. Pharmaceutical.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	In case of fire, use dry chemical, carbon dioxide, water spray or regular foam. For larger fires, use water spray, fog or regular foam to extinguish.
Unsuitable extinguishing media	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Vapor	Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

5.3 Advice for firefighters

Special protective equipment for fire-fighters	Wear self contained breathing apparatus for fire fighting if necessary. Avoid (reject) fire-fighting water to enter environment. Prevent entry to sewers and public waters

6. ACCIDENTAL RELEASE MEASURES

General	Remove ignition sources. Evacuate area.

6.1 Personal precautions, protective equipment and emergency procedures

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environment precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3 Methods and materials for containment and cleaning up

Clean spills promptly. To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal refer section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in 15°C to 30°C place. Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

No data available

8.2 Exposure controls

Appropriate engineering control

Keep in a well-ventilated room. Use only in an exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

Personal Protective Equipment

Respiratory protection Wear approved mask (P3). In case of insufficient ventilation, wear suitable respiratory equipment.

Hand protection Chemically resistant protective gloves.

Eye protection Chemical goggles or safety glasses.

Skin and body protection Use chemically protective clothing.

Hygiene measures General industrial hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance White to almost white crystalline powder

pH No data available

Odour Odourless

Melting Point Around 130° C to 145° C

Boiling point/range No data available

Flash point No data available

Evaporation rate No data available

Flammability (solid, gas) No data available

Upper/lower flammability limit No data available

Vapour pressure No data available

Vapour density No data available

Relative density No data available

Solubility Water – Insoluble
Acetone – Sparingly Soluble
Alcohol – Sparingly Insoluble

Partition coefficient No data available

Auto-ignition temperature Product does not self-ignite.

Decomposition temperature No data available

Viscosity No data available

Explosive properties Product does not present an explosion hazard

Oxidising properties No data available

9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical Stability

Stable.

10.3 Possibility of hazardous reactions
No data available.
10.4 Conditions to avoid
Heat, Direct sunlight.
10.5 Incompatible materials
Strong oxidant, fire and explosion hazard.
10.6 Hazardous decomposition products
Thermal decomposition product and toxic oxides of carbon.

11. Toxicological Information	
<i>Acute toxicity</i>	LD 50- Oral-rat-> 2 gm/kg
<i>Skin Corrosion/Irritation</i>	No data available
<i>Serious Eye Damage/Irritation</i>	No data available
<i>Respiratory or Skin Sensitization</i>	No data available
<i>Germ Cell Mutagenicity</i>	No data available
<i>Reproductive Toxicity/Teratogenicity</i>	May damage fertility or the unborn child.
<i>STOT-single exposure</i>	No data available
<i>STOT-repeated exposure</i>	No data available
<i>Aspiration hazard</i>	No data available
<i>Carcinogenicity</i>	No data available
<i>Potential health effects</i>	
<i>Inhalation</i>	Not dangerous goods.
<i>Ingestion</i>	Not dangerous goods.
<i>Skin</i>	Not dangerous goods.
<i>Eyes</i>	Not dangerous goods.
<i>Signs and Symptoms of Exposure</i>	Not dangerous goods.
<i>Additional Information</i>	Not dangerous goods.

12. Ecological Information
No Data Available

13. DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
<i>Product</i>	Observe all federal, state and local environmental regulations. This product contains hazardous components for the environment. Avoid release to the environment.
<i>Contaminated packaging</i>	Dispose its container at hazardous or special waste collection point.

14. TRANSPORTATION	
14.1 UN number	No data available
14.2 UN proper shipping name	
<i>ADR/RID</i>	Not dangerous goods.
<i>IMDG</i>	Not dangerous goods.
<i>IATA</i>	Not dangerous goods.
14.3 Transport Hazard Class(es)	Not applicable
14.4 Packaging group	Not applicable
14.5 Environmental hazards	No hazard identified

14.6 Special precaution for user	No data available

15. REGULATORY INFORMATION
Labeling according to EC Directives.
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available
15.2 Chemical safety assessment
No data available

16. OTHER INFORMATION	
Indication of changes: all the sections are updated according to ECHA Guidance	
Abbreviations and acronyms:	
a. CAS NO	: Chemical abstracts service number
b. EC	: European Commission
c. CLP	: Classification Labelling And Packaging Regulation
d. STOT	: Specific target organ toxicity
e. LD50	: Lethal dose
f. ECHA	: European Chemicals Agency
Additional information:	
The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the mentioned product, storage, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other product or in the case of processing, the information the material safety data sheet is not necessarily valid for the new made-up material.	

Material Safety Data Sheet

1. IDENTIFICATION OF SUBSTANCE AND SUPPLIER

Name On Label: Clomifene Citrate

Supplier: M/s. Bioxera Pharma Pvt Ltd,

N-57, MIDC, Addl. Ambernath, Ambernath (E)

Thane District, Pin code : 421 501, Maharashtra state, India.

Alternative Names: None in common use.

2. COMPOSITION AND INFORMATION ON COMPONENTS

Name: Clomifene Citrate

Minor Impurities : Not determined

CAS Number: 50-41-9

EC Number: 200-035-3

3. HAZARDS IDENTIFICATION

Designation:

Reproductive toxicity(category 2)

Risk Phrases

May impair fertility. Possible risk of harm to the unborn child.

4. FIRST AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing give artificial respiration Consult a physician.

In case of Skin Contact

Wash off with soap and plenty of water. Consult a physician.

In case of Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and Consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special Protective Equipment for Fire-fighters

Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal Protection

Wear personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental Protection

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

7. HANDLING AND STORAGE

Precaution for safe Handling

Avoid formation of dust and aerosols. Avoid exposure-obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Storage

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Protect from moisture.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Respiratory

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100(US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls.

Eye Protection

Safety glasses with side-shields conforming to EN166

Hand Protection

The selected protective gloves have satisfy the specifications of EU directive 89/686/EEC and standard EN374 derived from it.

Skin and body Protection

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene Measures

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: A white or pale yellow crystalline powder.

Physical Constants: M.P-not available

Molecular Formula: C₂₆H₂₈ClNO, C₆H₈O₇

Formula Weight: 598.08 g/mol.

Water Solubility: Slightly soluble in water

Density: Not available

10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions

Materials to avoid

Strong oxidizing agents

Hazardous decomposition products

Hazardous decomposition products formed under fire condition -carbon oxides, nitrogen oxides;
Hydrogen chloride gas.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

LD50 : Oral – rat-5,750 mg/kg

Skin corrosion/irritation

No data available

Carcinogenicity:

This product is not classified to its carcinogenicity based on its IARC, ACGIH, NTP or EPA classification

Reproductive toxicity

Possible risk of congenital malformation in the fetus.

Suspected human reproductive toxicant. May cause reproductive disorders.

12. ECOLOGICAL EFFECTS

Toxicity: no data available.

13. DISPOSAL CONSIDERATIONS

Product:

Observe all federal state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contamination packing:

Dispose of as unused product.

14. TRANSPORT INFORMATION

ADR/RID : Not dangerous goods

IMDG: Not dangerous goods

IATA : Not dangerous goods

15. REGULATORY INFORMATION

CAS Number: 50-41-9

EC Number: 200-035-3

UN Number: None

This safety datasheet complies with the requirements of Regulation (EC) No.1907/2006.

16. OTHER INFORMATION

Text of H-codes and R-phrase mentioned in section 3

H361 : Suspected of damaging fertility or the unborn child

Repr. : Reproductive toxicity

T : Toxic

R60 : May impair fertility

R63 : Possible risk of harm to the unborn child.

1. Product and Company Identification

Common name: Erythromycin
 Manufacturer: Linaria Chemicals (Thailand) Ltd.
 Address: 309 Bangpoo Industrial Estate, Soi 6C
 Sukhumvit Road, Moo 4, Tumbol Phraksa
 Ampur Muangsamutprakan, Samutprakan, Thailand 10280
 Tel: (662) 3240478-80

2. Composition / Information on Ingredients

Common name: Erythromycin
 Formula: $C_{27}H_{47}NO_{13}$
 Chemical name: Erythromycin
 Synonyms: n/a
 CAS number: 114-07-8
 RTECS number: KF4375000
 Chemical Family: A Macrolide antibiotic
 Therapeutic Category: Antibacterial
 Composition: Pure material

3. Hazards Information

Inhalation: Remove to fresh air. If breathing becomes difficult, call a physician.
 Eyes: Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes.
 Skin: Flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes.
 Ingestion: Wash out mouth with water provided person is conscious.

4. First Aid Measures

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.

Over dose Treatment: Recommended overdose treatment includes the following;

1. Evacuate the stomach to eliminate unabsorbed material.
2. Administer epinephrine, corticosteroids, and antihistamines for allergic reactions.
3. Use supportive measures as needed. [USP 32th ed. 2009]

5. Fire Fighting Measures

Extinguishing media: Carbon dioxide. Dry chemical powder. Appropriate foam.
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. Accidental Release Measures

Wear appropriate approved respirator, protective gloves, rubber boots, chemical safety goggles or other protective equipment.
Minimize direct contact with skin or eyes and prevent inhalation of dust. Sweep up, place in a bag and hold for waste disposal.
Avoid raising dust. Ventilate area and wash spill site with water after material pick up is complete.

7. Handling and Storage

Handling: Mechanical exhaust required. Do not breathe dust. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.
Storage: Store in well closed container, protected from light at temperature not exceeding 30 °C.

8. Exposure Controls/Personal Protection

Respiratory Protection: An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.
Ventilation: No special ventilation requirements.
Hand protection: Protective gloves (rubber).
Eye protection: Chemical safety goggles.
Other protective clothing or Equipment: Wear appropriate body coverings if contact may occur.

9. Physical and Chemical Properties

Appearance: White or slightly yellow crystalline powder
Odor: Odorless or practically odorless
Solubility: Freely soluble in alcohol. Soluble in methanol. Slightly soluble in water (the solubility decreases as the temperature rises).
Boiling point: n/a
Specific gravity (H₂O=1): n/a
Vapor Pressure (mmHg): n/a
Percent Volatile by volume (%): n/a
Vapor density (Air=1): n/a
Evaporation rate: n/a
Reactivity in water: n/a
Flash point: n/a

10. Stability and Reactivity

Stability	Stable
Conditions to avoid	Material is stable from safety point of view.
Incompatibility (material to avoid)	Volatile or organic solvents and acids
Hazardous decomposition products	When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.
Hazardous Polymerization	Will not occur

11. Toxicological Information

RTECS number:	KF4375000
Oral Rat	LD ₅₀ 4600 mg/kg

12. Ecological Information

Ecological Information	n/a

13. Disposal Considerations

Disposal	Incinerate in an approved facility. <i>Observe all federal state and local environmental regulations.</i>

14. Transport Information

This product is not subject to the regulations for the safe transport of hazardous chemicals
 DOT: Not regulated
 TDG: Not regulated
 IATA: Not regulated
 IMDG: Not regulated

15. Regulatory Information

Not applicable

16. Other Information

Revision date	08-Feb-2022
Previous Revision-06	01-Nov-2019

n/a = not applicable

Signature: *[Signature]*
Effective Date: 05/06/2017
Next Review Date: 06/05/2019

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LOHITHA LIFE SCIENCE PVT LIMITED

MATERIAL SAFETY DATA SHEET

Page: 1 of 7

DOMPERIDONE

MSDS NUMBER	SHE/MSDS/DP	VERSION	01
EFFECTIVE DATE	09/07/2015	REVIEW DATE	08/06/2017
DEPARTMENT	Safety, Health & Environment	SUPERSEDES	Not applicable

1. Product and Company Identification

Product name: Domperidone

Company : LOHITHA LIFESCIENCES PVT. LTD.

Plot No. 80 B, J.N. Pharma city,
Parawada Mandal, Visakhapatnam.

Telephone : +91 8498058780

2. Composition/Information on Ingredients

C.A.S. No: 57808-66-9

Product Group: antiemetic

3. Hazards Identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Reproductive toxicity (Category 2)

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Possible risk of impaired fertility. Possible risk of harm to the unborn child.

4. First-Aid Measures

Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

PREPARED BY	REVIEWED BY	APPROVED BY
<i>[Signature]</i> 06/07/2015	<i>[Signature]</i> 07/07/15	<i>[Signature]</i> 08/07/15
G.M.V.KRISHNA	S.VENKATESWARARAO	M.CHENNARAO
CHEMIST	SR.CHEMIST	MANAGER-QA

Signature : *[Signature]*
 Effective Date : 05/06/2017
 Next Review Date : 05/05/2019

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 LOHIT LIFE SCIENCE PVT LIMITED	MATERIAL SAFETY DATA SHEET		Page: 2 of 7
	DOMPERIDONE		
MSDS NUMBER	SHE/MSDS/DP	VERSION	01
EFFECTIVE DATE	09/07/2015	REVIEW DATE	08/06/2017
DEPARTMENT	Safety, Health & Environment	SUPERSEDES	Not applicable

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.
 Consult a physician.

Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been Thoroughly investigated.

Indication of any immediate medical attention and special treatment needed

no data available

5. Fire Fighting Measures

Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas

Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

Further information

No data available

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas.

Ensure

Adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

PREPARED BY	REVIEWED BY	APPROVED BY
<i>[Signature]</i> 06/07/2015	<i>[Signature]</i> 08-07-15	<i>[Signature]</i> 08-07-15
G.M.V.KRISHNA	S.VENKATESWARARAO	M.CHENNARAO
CHEMIST	SR.CHEMIST	MANAGER-QA

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Next Review Date : 04/05/2019

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MSDS NUMBER	SHE/MSDS/DP	VERSION	01
EFFECTIVE DATE	09/07/2015	REVIEW DATE	08/06/2017
DEPARTMENT	Safety, Health & Environment	SUPERSEDES	Not applicable

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed Containers for disposal.

Reference to other sections

For disposal see section 13.

7. Handling And Storage

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for Preventive fire protection.

Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Specific end uses

no data available

8. Exposure Control/Personal Protection

Eye/face protection

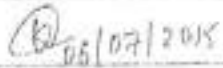
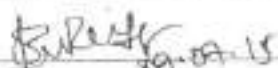
Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested And approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (Without touching glove's outer surface) to avoid skin contact with this product. Dispose of Contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and The standard EN 374 derived from it.

Immersion protection

PREPARED BY	REVIEWED BY	APPROVED BY
 05/07/2015	 08-07-15	 08-07-15
G.M.V. KRISHNA	S. VENKATESWARARAO	M. CHENNARAO
CHEMIST	SR. CHEMIST	MANAGER-QA

Effective Date : 05/06/2019

Next Review Date : 04/05/2019



LOHITHA LIFE SCIENCE PVT LIMITED

MATERIAL SAFETY DATA SHEET

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DOMPERIDONE

MSDS NUMBER	SHE/MSDS/DP	VERSION	01
EFFECTIVE DATE	09/07/2015	REVIEW DATE	08/06/2017
DEPARTMENT	Safety, Health & Environment	SUPERSEDES	Not applicable

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: > 480 min

Material tested: Dermatrill? (Anonymous Z677272, Size M)

Splash protection

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: > 30 min

Material tested: Dermatrill? (Anonymous Z677272, Size M)

Data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 873000, e-mail sales@kcl.de,

Test method: EN374

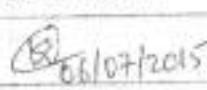
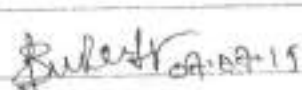
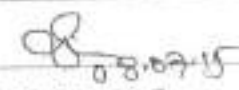
If used in solution, or mixed with other substances, and under conditions which differ from EN 374, Contact the supplier of the CE approved gloves. This recommendation is advisory only and must Be evaluated by an Industrial Hygienist familiar with the specific situation of anticipated use by our Customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Impervious clothing, the type of protective equipment must be selected according to the Concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle Respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering Controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use Respirators and components tested and approved under appropriate government standards such As NIOSH (US) or CEN (EU).

PREPARED BY	REVIEWED BY	APPROVED BY
		
G.M.V.KRISHNA	S.VENKATESWARARAO	M.CHENNARAO
CHEMIST	SR.CHEMIST	MANAGER-QA

Signature : 
Effective Date : 05/06/2017
Next Review Date : 05/06/2019

MATERIAL SAFETY DATA SHEET

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LORITHA LIFE SCIENCE PVT LIMITED

DOMPERIDONE

MSDS NUMBER	SHE/MSDS/DP	VERSION	01
EFFECTIVE DATE	09/07/2015	REVIEW DATE	08/06/2017
DEPARTMENT	Safety, Health & Environment	SUPERSEDES	Not applicable

9. Physical and Chemical Properties

Solid.

Does not mix with water.

State Divided solid Molecular Weight 425.9

Melting Range (°F) 468.5 Viscosity Not Applicable

Boiling Range (°F) Not applicable Solubility in water (g/L) Partly miscible

Flash Point (°F) Not available pH (1% solution) Not available

Decomposition Temp (°F) Not available pH (as supplied) Not applicable

Autoignition Temp (°F) Not available Vapour Pressure (mmHG) Negligible

Upper Explosive Limit (%) Not available Specific Gravity (water=1) Not available

Lower Explosive Limit (%) Not available Relative Vapor Density (air=1) Not Applicable

Volatile Component (%vol) Negligible Evaporation Rate Not Applicable

APPEARANCE: White to off white odorless, crystalline powder; does not mix well with water.

10. Stability and Reactivity

Chemical Stability:

Stable under normal temperatures and pressures.

Conditions to Avoid:

Incompatible materials, strong oxidants.

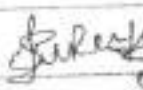
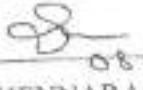
Incompatibilities with Other Materials:

Strong oxidizing agents, strong bases.

Hazardous Decomposition Products:

Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide, nitrogen

Hazardous Polymerization: Has not been reported.

PREPARED BY	REVIEWED BY	APPROVED BY
 06/07/2015	 08-08-15	 08-08-15
G.M.V.KRISHNA	S.VENKATESWARARAO	M.CHENNARAO
CHEMIST	SR.CHEMIST	MANAGER-QA

Effective Date: 05/06/2017
Review Date: 04/05/2019

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MATERIAL SAFETY DATA SHEET

Page: 6 of 7

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LOHITHA LIFE SCIENCE PVT LIMITED

MSDS NUMBER	SHE/MSDS/DP	VERSION	01
EFFECTIVE DATE	09/07/2015	REVIEW DATE	08/06/2017
DEPARTMENT	Safety, Health & Environment	SUPERSEDES	Not applicable

11. Toxicological Information

RTECS#:CAS#: LD50/LC50:

CAS#:Draize test, rabbit, eye: 100 mg/24H Moderate; Oral,

mouse: LD50 = 300 mg/kg; Oral, rabbit: LD50 = 3200 mg/kg; Oral, rat:

LD50 = 980 mg/kg.

Carcinogenicity: Salicylamide -Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.

See actual entry in RTECS for complete information.

12. Ecological Information

Do not allow product to enter drinking water supplies, waste water or soil!

13. Disposal Considerations

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber.

Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

14. Transport Information

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

15. Regulatory Information

European/International Regulations

European Labeling in Accordance with EC Directives

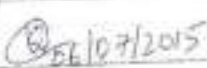
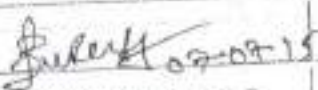
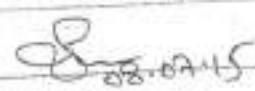
Hazard Symbols: XN

Risk Phrases:

R 22 Harmful if swallowed.

Safety Phrases:

WGK (Water Danger/Protection)

PREPARED BY	REVIEWED BY	APPROVED BY
 G.M.V.KRISHNA	 S.VENKATESWARARAO	 M.CHENNARAO
CHEMIST	SR.CHEMIST	MANAGER-QA

Effective Date : 05/06/2017

Next Review Date : 04/05/2019

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 LOHITHA LIFE SCIENCE PVT LIMITED	MATERIAL SAFETY DATA SHEET		Page: 7 of 7
	DOMPERIDONE		
MSDS NUMBER	SHE/MSDS/DP	VERSION	01
EFFECTIVE DATE	09/07/2015	REVIEW DATE	08/06/2017
DEPARTMENT	Safety, Health & Environment	SUPERSEDES	Not applicable

CAS# United Kingdom Occupational Exposure Limits

United Kingdom Maximum Exposure Limits

Canada

CAS# is listed on Canada's DSL List.

CAS# is not listed on Canada's Ingredient Disclosure List.

Exposure Limits

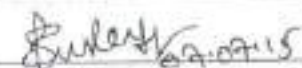
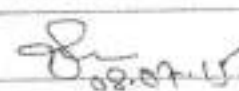
US FEDERAL

TSCA

CAS# is listed on the TSCA inventory

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

PREPARED BY	REVIEWED BY	APPROVED BY
 06/07/2015	 07/07/15	 08/07/15
G.M.V. KRISHNA	S. VENKATESWARARAO	M. CHENNARAO
CHEMIST	SR. CHEMIST	MANAGER-QA



MATERIAL SAFETY DATA SHEET

Title : Fexofenadine Hydrochloride			D.C. No. : MSDS-API-003
Prepared by (Sign./date) <i>[Signature]</i> 14/05/19			Revision No. : 01
Reviewed by (Sign./date) <i>[Signature]</i> 14/05/19			Page No. : 1 of 5
Approved by (Sign./date) <i>[Signature]</i> 14/05/19			Effective Date : 15/05/2019
Sr. Officer QA	Dy. Manager QA	AGM- QA	

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/SUPPLIER	
Trade Name	: Fexofenadine Hydrochloride
Uses of the substance	: Manufacturing of drug product
Manufacturer and Supplier	: Ind-Swift Laboratories Limited Phase-I, Industrial Growth Centre (SIDCO), Samba (J&K) India Tel.: ++91-1923-243270, 243293
2. HAZARDS IDENTIFICATION	
Hazard Pictogram	: No Symbol
Signal Word	: Warning
Hazard Statement	: H303 : May be harmful if swallowed H332 : Harmful if inhaled H313 : May be harmful in contact with skin H319 : Causes serious eye irritation
Precautionary Statements	: P261 : Avoid breathing dust/mist vapors P337+P313 : If eye irritation persists: Get medical advice/attention.
Special Health Hazards	: Adverse effect may include back pain, dizziness, growiness, painful menstruation, fatigue, headache, indigestion, nausea and sinusitis, cold or flu.
Ecological Hazards	: Emit toxic fumes under fire conditions
Chemical and Physical Hazards	: Incompatible with oxidizing agents

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Ind-Swift

Ind-Swift Laboratories Limited
Samba

RESTRICTED CIRCULATION

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SAFETY DATA SHEET

Title : Fexofenadine Hydrochloride		Rev. No. : 01	Page No. : 2 of 5
3. COMPOSITION/INFORMATION ON HAZARDOUS INGREDIENTS			
Chemical Name	:	2-[4-[(1 <i>RS</i>)-1-Hydroxy-4-[4-hydroxydiphenylmethyl]piperidin-1-yl]butyl]phenyl]-2-methylpropanoic acid hydrochloride	
		Or	
		Benzenecetic acid, 4-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]butyl]- α,α -dimethyl-, hydrochloride, ($\pm$)-.	
Content	:	Pure	
CAS No.	:	[153439-40-8] Ph.Eur. [138452-21-8] USP	
EC No.	:	n/f	
Index No.	:	n/f	
Molecular Formula (HILL)	:	$C_{22}H_{40}ClNO_4$	
Molecular Weight	:	538.1	
Synonym	:	Carboxyterfenadine Hydrochloride	
4. FIRST AID MEASURES			
After Inhalation	:	Remove to fresh air. If you feel unwell, seek medical advice.	
After Skin Contact	:	Remove affected clothing and wash all exposed skin area with mild soap and water.	
After Eye Contact	:	Flush with copious quantities of water. Obtain medical attention	
After Swallowing	:	Flush out mouth with water. This material is rapidly absorbed from the gastrointestinal tract, seek medical advice.	
5. FIRE-FIGHTING MEASURES			
Suitable Extinguishing Media	:	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.	
Unsuitable Extinguishing Media	:	n/f	
Special Risks	:	Combustible	
Special Protective Equipment for Fire-Fighting	:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.	

C:\Program Files\MSN Software\MSN Messenger\MSN Messenger.exe

015_64.doc



SAFETY DATA SHEET

Title : Fexofenadine Hydrochloride		Rev. No. : 01	Page No. : 3 of 5
6. ACCIDENTAL RELEASE MEASURES			
Person-Related Precautionary Measures	: Remove from exposure, remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If breathing is difficult give artificial respiration and oxygen		
Environmental-Protection Measures	: Dispose of waste in accordance with all applicable Federal, State and Local Laws		
Procedures for Cleaning/Absorption	: Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site		
7. HANDLING AND STORAGE			
Handling	: As a general rule, when handling Fexofenadine Hydrochloride avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.		
Storage	: Preserve in well-closed, light-resistant container and store at controlled room temperature. This material should be handled and stored as per label instructions to ensure product integrity.		
8. EXPOSURE CONTROLS/PERSONAL PROTECTION			
Specific Control Parameter-MDK : n/f			
Industrial Hygiene	: Provide local exhaust or general room ventilation. Change contaminated clothing. Flush eyes with water and wash contaminated areas of body with soap and water.		
Respiratory Protection	: The use of an approved dust mask is recommended.		
Hand Protection	: Wear suitable gloves resistant to chemical penetration.		
Eye Protection	: Wear safety glasses or goggles		
Skin Protection	: Protect exposed skin, wear aprons		



Ind-Swift

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SAFETY DATA SHEET

Title. :Fexofenadine Hydrochloride		Rev. No. : 01	Page No. : 4 of 5
9. PHYSICAL AND CHEMICAL PROPERTIES			
Form/Colour	:	White or almost white powder.	
Odour	:	Odorless	
Boiling Point (°C)	:	n/f	
Melting range (°C)	:	191-198°C	
Vapour Pressure	:	n/f	
Flash Point	:	n/f	
Ignition Temperature	:	n/f	
Explosion Limits	:	n/f	
Density	:	n/f	
pH Value	:	n/f	
Solubility in Water	:	Slightly soluble in water.	
Solubility in Other Substances	:	Freely soluble in methanol, very slightly soluble in acetone.	
Log P Octanol/water at 20°C	:	0.3	
10. STABILITY AND REACTIVITY			
Stability	:	Stable under normal condition	
Hazardous Reactions	:	Material may decompose emitting toxic fumes of NO _x and HCl when heated.	
Conditions to be Avoided	:	Heat. Source of ignition. Sparks	
Chemicals to be avoided	:	Oxidizing agent	
Hazardous Decomposition Products	:	When heated to decomposition, emits toxic fumes.	
11. TOXICOLOGICAL INFORMATION			
LD ₅₀ (Oral Rat)	:	>5146 mg/Kg	
LD ₅₀ (Oral Mouse)	:	n/f	
LD ₅₀ (Dermal)	:	n/f	
LD ₅₀ (Inhalation)	:	n/f	
Short-Term Exposure Effects (Effects and Symptoms)	:	Possible eye, skin, gastrointestinal and/or respiratory tract irritation	
Long-Term Exposure Effects (Effects and Symptoms)	:	Possible hypersensitization and impaired kidney function	

File Name : E:\Gambhara\Data\SLI\DOA Data\MSDS\Company\MSDS\SDS_Euro\Euro-Fine-HCL-EDP_73

015_04.doc



SAFETY DATA SHEET

Title : Fexofenadine Hydrochloride	Rev. No. : 01	Page No. : 5 of 5
12. ECOLOGICAL INFORMATION		
Ecological effects information	: No data available	
LC50-96 Hour – fish [mg/L]	: >940	
EC50-48 Hour-Daphnia magna [mg/L]	: >780	
IC50-72h-Algae [mg/L]	: No data available	
Biodegradation	: Readily biodegradable	
Persistence - degradability	: No data available	
Log P octanol / water at 20°C	: No data available	
Bioaccumulative potential	: No data available	
13. DISPOSAL CONSIDERATIONS		
Product	: Dispose in compliance with local state and federal laws and regulations	
Packaging	: Keep spills in a labeled and tightly closed container	
14. TRANSPORT INFORMATION		
Proper Shipping Name	:	Not classified as hazardous for transport
Road Transport ADR, UN No.	:	
Rail Transport RID, UN No.	:	
Sea Transport IMDG, UN No.	:	
Air Transport IATA/ICAO, UN No.	:	
15. REGULATORY INFORMATION		
R-Phrases	: R36/37/38 – Irritating to eyes/respiratory system/skin	
S-Phrases	: S7 – Keep container tightly closed	
	S22- Do not breathe dust.	
	S24/25 – Avoid contact with skin and eyes	
	S36/37 – Wear suitable protective clothing/gloves	
EU Regulations	: No REACH Annexure-XVII restrictions	
US Federal Regulations	: CERCLA/SARA hazardous substances: Not Applicable	
16. OTHER INFORMATION		
Revised in compliance with Regulation (EC) no. 1907/2006 (REACH)		
The information above is believed to be accurate and represents the best information currently available to us from internet. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use.		

ZHEJIANG ZHEBEI PHARMACEUTICAL CO., LTD

浙江浙北药业有限公司

Address: No.66,Guoshantou,Xinshi Town, Deqing, Zhejiang Province

E-MAIL:XSB@ZHEBEIPHARMA.COM

MATERIAL SAFETY DATA SHEET

Version Date 20/08/2021

Section 1: Chemical Product and Company Identification

Product Name: Acyclovir	Contact Information
Catalog Codes: SLA4732	Zhejiang Zhebei Pharmaceutical Co., Ltd. Sanlitang, Qianyuan Town, Deqing County, Zhejiang, CHINA, 313216 CHEMTREC (24HR Emergency Telephone), call:0086-572-8435629 For non-emergency assistance, call: 0086- 572-8435681
CAS#: 59277-89-3	
RTECS: UP0791400	
TSCA: TSCA 8(b) inventory: No products were found	
CI#: Not available.	
Synonym: Zovirax, Aciclovir; 9-[(2-1-800-424-9300 Hydroxyethoxy)methyl]guanine; Acycloguanosine	
HEMTREC, call: 1-703-527-3887 Chemical Name: 6H- Purin-6-one, 1,9-dihydro-2-amino-9-[(2- HYDROXYETHOXY)METHYL]-	
Chemical Formula: C ₈ H ₁₁ N ₅ O ₃	

Section 2: Composition and Information on Ingredients

Composition:		
Name	CAS #	%BY WEIGHT
Acyclovir	59277-89-3	100
Toxicological Data on Ingredients: Acyclovir: ORAL (LD50): Acute: > 20000 mg/kg [Rat]. > 10000 mg/kg [Mouse].		

Section 3: Hazards Identification**Potential Acute Health Effects:**

Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects: CARCINOGENIC EFFECTS: 3 (Not classifiable for human.) by IARC. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

Section 4: First Aid Measures

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Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. WARM water MUST be used. Get medical attention.

Skin Contact:

In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:

Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration.

If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel.

Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂).

Fire Hazards in Presence of Various Substances: Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances: Risks of explosion of the product in presence of mechanical impact: Not available. Slightly explosive in presence of open flames and sparks.

Fire Fighting Media and Instructions: SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards:

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Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard

Section 6: Accidental Release Measures

Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions: Keep locked up.. Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available

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Section 9: Physical and Chemical Properties

Physical state and appearance: Solid (Crystalline powder).

Odor: Not available.

Taste: Not available.

Molecular Weight: 225.2 g/mole

Color: White. Off-white.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: 257°C (494.6°F)

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Very slightly soluble in cold water, methanol. Solubility in Water:

1.3mg/ml Solubility in Methanol: 0.2mg/ml

Section 10: Stability and Reactivity data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, excess dust generation.

Incompatibility with various substances: Not available.

Corrosivity: Not available.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): >10000 mg/kg [Mouse].

Chronic Effects on Humans:

CARCINOGENIC EFFECTS: 3 (Not classifiable for human.) by IARC.

MUTAGENIC EFFECTS:

Mutagenic for mammalian

somatic cells.

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Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: May cause adverse reproductive effects and birth defects (teratogenic)

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: May cause eye irritation. Inhalation: May cause respiratory tract irritation. Ingestion: May cause gastrointestinal tract irritation with abdominal pain, nausea, vomiting, diarrhea or decreased motility or constipation. May affect behavior/central nervous system(hallucinations, convulsions, muscle contraction or spasticity, somnolence, dizziness, vertigo, headache, lethargy, tremors, confusion, seizures, delirium, jitters, lightheadedness, obtundation, fatigue, insomnia, irritability, mental depression, antipsychotic, coma), brain, respiratory system (sputum), blood (agranulocytosis, thrombocytopenia, leukopenia, thrombocytosis, lymphopenia), urinary system (kidney failure, acute tubular necrosis). Other symptoms may include sore throat, thirst, muscle cramps, perspiration, fever, lymphadenopathy, substernal burning sensation, leg pain, hematuria, hypotension, heart palpitation, bone marrow hypoplasia. May cause allergic dermatitis with urticarial or rash, acne
Chronic Potential Health Effects: Ingestion: Prolonged or repeated ingestion may affect the urinary system, and metabolism (anorexia).

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal: Waste must be disposed of in accordance with federal, state and local environmental control regulations

Section 14: Transport Information

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14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

Section 15: Other Regulatory Information

Federal and State Regulations: No products were found.

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): R36/38-Irritating to eyes and skin. R40-Possible risks of irreversible effects. S2-Keep out of the reach of children. S36/37-Wear suitable protective clothing and gloves. S46-If swallowed, seek medical advice immediately and show this container or label.

HMIS (U.S.A.)

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment: Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Splash goggles.

SECTION 16 Additional Information Key to Abbreviations

ACGIH -American Conference of Governmental Industrial Hygienists HEPA -

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High Efficiency Particulate Air IARC -International Agency for Research on
Cancer NA -Not Applicable NE -Not Established NG -Not Given NIOSH -
National Institute for Occupational Safety and Health NTP -National
Toxicology Program OEL -Occupational Exposure Limit OSHA -Occupational
Safety and Health Administration PEL -Permissible Exposure Limit PPM -
Parts Per Million QS -Quantity Sufficient RCRA -Resource Conservation and
Recovery Act STEL -Short Term Exposure Limit TLV -Threshold Limit Value
USP -United States Pharmacopeia

Disclaimer: The information contained herein pertains to this material. It is the
responsibility of each individual party to determine for themselves the proper
means of handling and using these materials based on their purpose and
intended use. Zhejiang Zhebei Pharmaceutical Co., Ltd. assumes no liability
resulting from the use of or reliance upon the information contained in this
material safety data sheet. This material safety data sheet does not constitute
the guaranty or specifications of the product.

Effective Date: 29.02.2016
Revision: 3.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
1.1. Product identifier

Trade name: Azathioprine
CAS-number: 446-86-6

Reach registration number: NA

1.2. Relevant identified uses of the substance or mixture and uses advised against

The uses of the chemical: Active pharmaceutical ingredients
Classification of the economic activities (NACE): 212
Use categories (UC62): 41

1.3. Details of the supplier of the safety data sheet:

Manufacturer/importer: Fermion Oy
Street address: Koivu-Mankkaan tie 6 A
Post-office box: P.O. Box 28
Postcode: 02101 Espoo, Finland
Telephone number: +358 10 4261
Telefax: +358 0 9452 1764
E-mail address: chemicalsafety@orion.fi
VAT Reg. No: FI18552129

1.4. Emergency telephone number

Poison Center: +358 9 471 977

SECTION 2: HAZARDS IDENTIFICATION
2.1. Classification of the substance or mixture:

Classification according to regulation EC 1272/2008	Acute Tox. 4	H302,
	Carc. 1B	H350,
	Muta. 1B	H340,
	Repr. 2	H361d,
	Eye Irrit. 2	H319,
	STOT SE 3	H335,
	Skin Irrit. 2	H315,
H Statements	Harmful if swallowed.	

Effective Date 29.02.2016
Revision 3.0

	May cause cancer. May cause genetic defects. Suspected of damaging the unborn child. Causes serious eye irritation. May cause respiratory irritation. Causes skin irritation.

2.2. Label elements

Hazard Pictograms



Signal word

Danger

H Statements

- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H340 May cause genetic defects.
- H350 May cause cancer.
- H361d Suspected of damaging the unborn child.

P Statements

- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P302+P352 IF ON SKIN: Wash with soap and water.
- P305+P351+P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do, continue rinsing.
- P280 Wear protective gloves/protective clothing/eye protection.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P501 Dispose of contents according to national and local law.

2.3. Other hazards

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Effective Date 29.02.2016
Revision 3.0

Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Azathioprine	446-86-6	207-175-4	NA

Request for Confidentiality by Annex 2 No
Substance indicated Confidential No
Other information -

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions	Helpers should ensure their own protection.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If appropriate, give artificial respiration or oxygen. If appropriate, give oxygen. Get medical advice/attention.
Skin contact	Remove/Take off immediately all contaminated clothing. IF ON SKIN: Wash with soap and water. If skin irritation occurs: Get medical advice/attention.
Eye contact	IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
Ingestion	Do NOT induce vomiting. Rinse mouth. If the patient is conscious, give plenty of water (2 - 4 glasses). Get medical advice/attention.

Effective Date 29.02.2016
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4.2. Most important symptoms and effects, both acute and delayed

See section 11 for symptoms of exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	Foam
	Water
	Powder
	Carbon dioxide

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters	Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.

6.2. Environmental precautions

Data not available.

6.3. Methods and material for containment and cleaning up

Collect spilled powder without dusting into tight closed container.

6.4. Reference to other sections

See Section 8 and 13

Effective Date: 29.02.2016
Revision: 3.0

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in well-ventilated space.
Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

Keep cool.
Store in a dry place.
Keep container tightly closed.
Protect from moisture.
Protect from sunlight.
See incompatible materials in section 10.5.

7.3. Specific end use(s)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values	-
DNELs	-
PNECs	-

8.2. Exposure controls

Appropriate engineering controls

Handle in well-ventilated space.
All exposure must be avoided.

Respiratory protection

In dust making work use respirator, filtration P3. In laboratories work in fume hood or under dust control hood.
See particular department's regulations of protection.

Hand protection

Use protective gloves (e.g. nitrile or neopren gloves).

Eye protection

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Use protective goggles.

Skin protection
Wear protective clothing.

Environmental exposure controls
Releases to the environment should be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state	Crystalline
Colour	Nearly white
Odour	Odourless
Odour threshold	-

9.1. Information on basic physical and chemical properties

pH Value	6 - 7
Melting point	224 °C

Water solubility	Insoluble

9.2. Other information

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

10.2. Chemical stability

Effective Date 29.02.2016
Revision 3.0

10.3. Possibility of hazardous reactions

-

10.4. Conditions to avoid

Moisture
Light

10.5. Incompatible materials

Strong oxidants

10.6 Hazardous decomposition products

May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity	Harmful if swallowed. LD50 = 400 mg/kg (rat, oral)
Skin irritation and corrosion	Causes skin irritation.
Skin sensitization	Data not available.
Serious eye damage and irritation	Causes serious eye irritation.
Respiratory irritation	May cause respiratory irritation.
Respiratory sensitization	Data not available.
Carcinogenicity	May cause cancer. The substance has been found carcinogenic in animal tests.
Germ cell mutagenicity	May cause genetic defects. Substance has been found mutagenic in animal tests.

Effective Date 29.02.2016
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Reproductive toxicity	Suspected of damaging the unborn child. TDLO = 15 mg/kg (rat, oral 6-8D preg) -> effects on fertility TDLO = 120 mg/kg (rat, oral 10-15D preg) -> effects on newborn
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	Long term or frequent contact may cause irritation.
Aspiration hazard	Data not available.
Repeated dose toxicity	Data not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

EC50: > 100 mg/l, 48 h, *Daphnia magna*, water flea

Toxic effects on other organisms

IC50: > 1000 mg/l, 3 h (Activated sludge)
IC50: > 100 mg/l, 72 h (*Scenedesmus subspicatus*)

12.2. Persistence and degradability

Not readily biodegradable.

12.3. Bioaccumulative potential

Octanol-water partition coefficient(KOW)	Data not available.
Bioconcentration factor	Data not available.

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12.4. Mobility in soil

Data not available.

12.5. Results of PBT and vPvB assessment

Data not available.

12.6. Other adverse effects

Data not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

SECTION 14: TRANSPORT INFORMATION

14.1. UN Number

14.2. UN Proper shipping name

14.3. Transport hazard class(es) (ADR/RID, IMDG, ICAO/IATA)

This product is not regulated under the transport regulations.

14.4. Packing group

14.5. Environmental hazard

Effective Date 29.02.2016
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14.6. Special precautions for user**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code**

Not applicable

SECTION 15: REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for substance or mixture**

The product has not been fully tested.

15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION**Further information**

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Fermion Oy shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the Safety Data Sheet

Information provided by the supplier

Information which has been added, deleted or revised

Updated section / sections:

8



BETAMETHASONE 17-VALERATE

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING	
<i>1.1 Product Identifier</i>	
<i>Substance Name</i>	Betamethasone 17-Valerate
<i>CAS-No</i>	2152-44-5
<i>EC-No.</i>	218-439-3
<i>1.2 Relevant identified uses of the substance or mixture and uses advised against</i>	
<i>Identified Uses</i>	Laboratory chemicals, Manufacture of substances
<i>1.3 Details of supplier of safety data sheet</i>	
<i>Company</i>	Symbiotica Speciality Ingredients Sdn. Bhd.
<i>Address</i>	13, Lorong Perusahaan Sungai Lokan 2, Taman Industri Sungai Lokan, 13800, Butterworth, Pulau Pinang, Malaysia
<i>Telephone</i>	+604-5189000
<i>Fax</i>	+604-3581700
<i>E-mail Address</i>	symbioti@symbiotica.com.my
<i>1.4 Emergency telephone number</i>	
<i>Emergency Phone</i>	+604-5189000
2. HAZARDS IDENTIFICATION	
<i>2.1 Classification of the substance or mixture</i>	
Classification according to Regulation (EC) No 1272/2008 (CLP)	
Repr.1B, STOT RE 2	
<i>2.2 Label elements</i>	
Classification according to Regulation (EC) No 1272/2008 (CLP)	
Hazard pictograms: GHS08: Health hazard	
	
<i>Signal Word</i>	
Warning	
<i>Hazards statement (s)</i>	
H360D: May damage the unborn child.	
H373: Causes damage to organs.	
<i>Precautionary statement (s)</i>	
P260: Do not breathe dust.	
P281: Use personal protective equipment as required.	
P314: Get medical advice/attention if you feel unwell.	
<i>2.3 Other hazards</i>	
None	

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

<i>Chemical Name</i>	9-Fluoro-11 β ,21-dihydroxy-16 β -methyl-3,20-dioxopregna-1,4-dien-17-yl pentanoate
<i>Synonyms</i>	1,4-Pregnadiene-11 β ,17 α ,21-triol-9 α -fluoro-16 β -methyl-3,20-dione 17-valerate,

	Belnovate, 9α-Fluoro-16β-methyl-11β,17α,21-trihydroxy-1,4-pregnadiene-3,20-dione 17-valerate. 9α-Fluoro-16β-methylprednisolone 17-valerate
<i>Formula</i>	C ₂₇ H ₃₇ FO ₆
<i>Molecular Weight</i>	476.58 g/mol
<i>Classification</i>	R _{6pr} , 1B; H360D, STOT RE 2; H373

4. FIRST AID MEASURES

4.1 Description of first aid measures

<i>General Advice</i>	Consult a physician. Show this safety data sheet to the doctor in attendance.
<i>If Inhaled</i>	Assure fresh air breathing. If you feel unwell, seek medical advice
<i>In Case of Skin Contact</i>	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
<i>In Case of eye contact</i>	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persists.
<i>If Swallowed</i>	Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.

4.2 Most important symptoms and effects, both acute and delayed

Convulsions, Headache, Electrolyte imbalance.

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent, Pharmaceutical.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

<i>Suitable extinguishing media</i>	Water spray, carbon dioxide and dry powder.
<i>Unsuitable extinguishing media</i>	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

<i>Vapor</i>	Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

5.3 Advice for firefighters

<i>Special protective equipment for fire-fighters</i>	Wear self contained breathing apparatus for fire fighting if necessary. Avoid (reject) fire-fighting water to enter environment. Prevent entry to sewers and public waters

6. ACCIDENTAL RELEASE MEASURES

<i>General</i>	Remove ignition sources. Evacuate area.

6.1 Personal precautions, protective equipment and emergency procedures

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environment precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3 Methods and materials for containment and cleaning up

Clean spills promptly. To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation.

6.4 Reference to other sections

For disposal refer section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
Recommended storage temperature: 15°C to 30°C

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**8.1 Control parameters**

No data available

8.2 Exposure controls**Appropriate engineering control**

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

Personal Protective Equipment

Respiratory protection	Wear approved mask (P3). In case of insufficient ventilation, wear suitable respiratory equipment.

Hand protection	Chemically resistant protective gloves.

Eye protection	Safety glasses.

Skin and body protection	Use chemically protective clothing.

Hygiene measures	General industrial hygiene measures.

9. PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

Appearance	White or almost white, crystalline powder

Melting Point	About 192°C

Solubility	Water - Practically insoluble Acetone - Freely soluble Methylene chloride - Freely soluble Ethanol (96%) - Soluble

9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY**10.1 Reactivity**

Stable under normal conditions.

10.2 Chemical Stability

Stable.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Direct sunlight. Sources of ignition.

10.5 Incompatible materials

Strong oxidizers.

10.6 Hazardous decomposition products

Carbon dioxide, Hydrogen fluoride, Carbon monoxide, Chlorides. When heated to decomposition, emits dangerous fumes.

11. TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects**

Acute toxicity	LD50 Oral - rat - > 3,000 mg/kg Endocrine disorders. May produce irregular heart beat and nervous symptoms.

	Oedema. Gastrointestinal disorders.
<i>Carcinogenicity</i>	Endocrine disorders
<i>Potential health effects</i>	
<i>Inhalation</i>	May be harmful if inhaled. May cause respiratory tract irritation.
<i>Ingestion</i>	May be harmful if swallowed.
<i>Skin</i>	May be harmful if absorbed through skin. May cause skin irritation.
<i>Eyes</i>	May cause eye irritation.
<i>STOT-repeated exposure</i>	Causes damage to organs through prolonged or repeated exposure.
<i>Chronic exposure</i>	Immune system suppression.
<i>Additional Information</i>	RTECS: TU3835000

12. ECOLOGICAL INFORMATION

12.1 Toxicity	General: Hazardous waste. Use suitable disposal containers.
12.2 Persistence and degradability	Minimally biodegradable.
12.3 Bioaccumulative potential	No data available
12.4 Mobility in Soil	No data available
12.5 PBT and vPvB assessment	No data available
12.6 Other adverse effects	EC50-48 Hour-Daphnia magna [mg/L]: 1.9

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
<i>Product</i>	Observe all federal, state and local environmental regulations.
<i>Contaminated packaging</i>	Disposed of as unused product.

14. TRANSPORTATION

14.1 UN number	No data available
14.2 UN proper shipping name	
<i>ADR/RID</i>	Not dangerous goods.
<i>IMDG</i>	Not dangerous goods.
<i>IATA</i>	Not dangerous goods.
14.3 Transport Hazard Class(es)	Not applicable
14.4 Packaging group	Not applicable
14.5 Environmental hazards	No hazard identified
14.6 Special precaution for user	No data available

15. REGULATORY INFORMATION

Labeling according to EC Directives.	
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
No data available	
15.2 Chemical safety assessment	
No data available	

16. OTHER INFORMATION

Indication of changes: all the sections are updated according to ECHA Guidance	
Abbreviations and acronyms:	
a. CAS NO	: Chemical abstracts service number
b. EC	: European Commission
c. CLP	: Classification Labelling And Packaging Regulation
d. STOT	: Specific target organ toxicity
e. LD50	: Lethal dose
f. RTECS	: Registry of Toxic Effects of Chemical Substances

g.	ECHA	European Chemicals Agency
h.	PBT	Persistent, Bioaccumulative and Toxic
i.	vPvB	very Persistent and very Bioaccumulative

Additional information:
The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the mentioned product, storage, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other product or in the case of processing, the information the material safety data sheet is not necessarily valid for the new made-up material.

 BAL PHARMA LIMITED, UNIT-II Bangalore	MATERIAL SAFETY DATA SHEET SAFETY, HEALTH & ENVIRONMENT ADAPALENE	MS / PP / 008
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Next Review date 30.12.2021		Effective date: 01.12.2018
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SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name : ADAPALENE
 Synonym : 2-Naphthalenecarboxylic acid, 6-(4-Methoxy-3-tricyclo [3.3.1.1^{2,7}]dec-1-ylphenyl)
 Chemical Name : 6-[3-(1-Admantyl)-4-methoxyphenyl]-2-naphthoic acid
 Chemical Formula : C₃₄H₃₀O₂

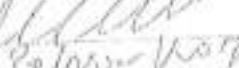
CONTACT INFORMATION:
 BAL PHARMA LIMITED, UNIT-II
 61-B, Bommarandra Industrial Area
 Bangalore - 560 099
 Tel: 080-41570814/15/16/17
 Fax: 080-41570812
 Email: unit2@balpharma.com

SECTION 2: COMPOSITION AND INFORMATION ON INGREDIENTS

Composition : Adapalene
 Composition : 99.5%
 CAS # : 106683-40-9
 Toxicological Data on Ingredients : Not available
 Hazard Symbols : Not available.

SECTION 3: HAZARDS IDENTIFICATION

Physicochemical effects : Mild irritation
 Human Health Effects : Should not be inhaled or swallowed
 Handling : To be handled using protective gear like gloves, nose mask etc.

	Prepared by	Checked by	Approved by
Signature			
Date	28/11/2018	29/11/2018	
Name	Mr. Nareshta N	Mr. Kannan.R.S.	Mr. Venkatesh.S.Rao
Designation	Officer-EHS	HOD-Safety	HOD-QA

MASTER COPY
 DATE
 01 DEC 2018

20 DEC 2018

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SECTION 4: FIRST AID MEASURES

Eye Contact	: Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.
Skin Contact	: Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse.
Ingestion	: Rinse the mouth with water and contact the Physician.
Inhalation	: Remove from exposure and move to fresh air immediately.
If breathing is difficult, give oxygen. If needed, contact the physician.	

SECTION 5: FIRE AND EXPLOSION DATA

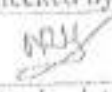
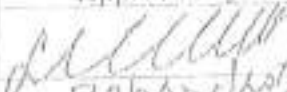
Flammability of the Product	: Flammable.
Suitable Extinguishing Media	: Dry chemical powder
Special Fire fighting procedure	: In case of fire, wear self contained breathing apparatus and a protective suit
Auto-Ignition Temperature	: Not applicable.
Flash Point	: No data available

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precaution safety	: Use proper personal protective equipment (Side covered goggles and lung protector) as indicated in Section 8. Avoid skin contact.

SECTION 7: HANDLING AND STORAGE

Handling	: Handle in accordance with good 'Industrial safety practices'. Should not be inhaled or swallowed.
Storage	: Store at room temperature 25 ± 5 °C in tight containers; protected from light.

	Prepared by	Checked by	Approved by
Signature			
Date	22/10/2018	22/10/2018	20/10/2018
Name	Mr. Naresha N	Mr. Kannan.R.S.	Mr. Venkatesh.S.Rao
Designation	Officer-EHS	HOD-Safety	HOD-QA

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DATE
01 DEC 2018

7 / DEC 2018

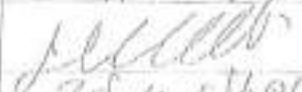
 P&S PHARMAS LIMITED, INDIA Bangalore	MATERIAL SAFETY DATA SHEET SAFETY, HEALTH & ENVIRONMENT ADAPALENE	MS / PP / 008
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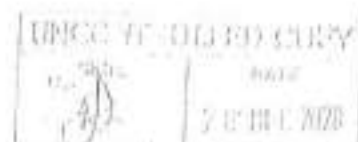
SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit values	: No data available.
Engineering Controls	: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use ventilation to keep airborne concentrations low.
Personal Protective Equipment	
Eyes	: Wear appropriate protective eyeglasses or chemical safety goggles.
Skin exposure	: Wear appropriate protective clothing to prevent skin exposure.
Hand	: Wear appropriate protective full length hand gloves.
Respirators	: Lung Protector with dust filter cartridge.
Ingestion	: Do not eat, drink or smoke while handling the product. Wash hands before breaks and immediately after handling the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical state and appearance	: White solid
Odor	: Slight characteristic odour.
Taste	: Not available.
Molecular Weight	: 412.52
Color	: White or Almost White powder
pH (1% solution)	: Not available.
Boiling Point	: Not available
Melting Point	: 318-320°C
Critical Temperature	: Not applicable
Specific Gravity	: Not applicable.
Vapor Pressure	: Not available
Vapor Density	: Not available
Bulk Density	: No data available
Volatility	: Not available
Odor Threshold	: Not available
Water/Oil Dist. Coeff.	: Not available
Ionicity (in Water)	: Not available

	Prepared by	Checked by	Approved by
Signature			
Date	28/11/2018	29/11/2018	30/11/2018
Name	Mr. Naresh N	Mr. Kannan, R.S.	Mr. Venkatesh S. Rao
Designation	Officer-EHS	HOD-Safety	HOD-QA



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Dispersion Properties : Not available
Solubility : Insoluble in water
Corrosivity : No data available
Partition coefficient(n-octanol/water): No data available

SECTION 10: STABILITY AND REACTIVITY DATA

Condition to avoid :
Temperature : Direct exposure to heat
Light : Direct exposure to light
Materials to avoid : No data available
Stability : Stable under normal temperatures and pressures.
Instability Temperature : Not available.
Conditions of instability : Incompatible materials, ignition sources, excess heat.
Incompatibility with various substances: Incompatibilities Hazardous combustion or decomposition products.
Corrosivity : No Data Available
Hazardous Decomposition Products: Oxides of carbon
Hazardous Polymerization : Has not been reported.

SECTION 11: TOXICOLOGICAL INFORMATION

No data available

Acute toxicity (oral, inhalation, dermal): LD50: Orally in Mice > 3000mg/kg.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity : No data available
Mobility : No data available
Persistence and degradability : No data available
Bio accumulative potential : No data available
Other adverse effects : No data available

Signature	Prepared by	Checked by	Approved by
			
Date	30.12.2018	30.12.2018	30.12.2018
Name	Mr. Naresha N	Mr. Kannan R.S.	Mr. Venkatesh S. Rao
Designation	Officer-EHS	HOD-Safety	HOD-QA



 SRI PHARMAS LIMITED, UNIT II Bangalore	MATERIAL SAFETY DATA SHEET SAFETY, HEALTH & ENVIRONMENT ADAPALENE	MS / FP / UOM
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SECTION 13: DISPOSAL CONSIDERATIONS

Product Disposal : Product in accordance with current local authority regulations.
 Contaminated packaging : Same as the product

SECTION 14: TRANSPORT INFORMATION

Packaging : Packed in pre-weighed double poly lined HDPE container (inner transparent and outer black polythene bag).

Land Transport ADR/RID/Cross-Border

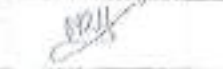
ADR/RID Class : Not classified for transport
 UN Number : Not applicable
 Packing Group : Not applicable
 Proper Shipping Name : Not applicable
 Label : Maritime (IMO)
 IMO Class : Not classified for transport
 UN Number : Not applicable
 Packing Group : Not applicable
 Proper Shipping Name : Not applicable

Air Transport ICAO/IATA

ICAO/IATA Class : Not classified for transport
 UN/IID Number : Not applicable
 Packing Group : Not applicable
 Correct Technical Name : Not applicable

SECTION 15: OTHER REGULATORY INFORMATION

General Health, safety and environmental information system on the table according to EU Directives:

	Prepared by	Checked by	Approved by
Signature			
Date	28/11/2018	29/11/2018	30/11/2018
Name	Mr. Naresha N	Mr. Kannan.R.S.	Mr. Venkatesh.S.Rao
Designation	Officer-EHS	HOD-Safety	HOD-QA



 RED PHARMA LIMITED, UNIT B Bangalore	MATERIAL SAFETY DATA SHEET	MS / SD / 008
Supersedes document 03	SAFETY, HEALTH & ENVIRONMENT	Revision No. 04
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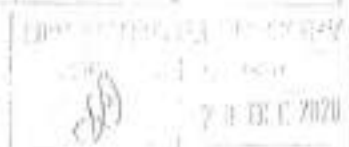
SECTION 16: REFERENCE:

In house sources:

Disclaimer:

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall Red Pharma Limited be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Red Pharma Limited has been advised of the possibility of such damages.

Signature	Prepared by	Checked by	Approved by
			
Date	28/11/2018	29/11/2018	30/11/2018
Name	Mr. Naresha N	Mr. Kannan.R.S.	Mr. Venkatesh.S.Rao
Designation	Officer-EHS	HOD-Safety	HOD-QA



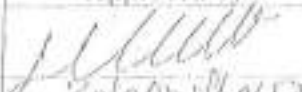
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SECTION 17: DISTRIBUTION

SL.NO.	COPY NAME	DEPARTMENT
1	Master Copy	QA
2	Controlled Copy	SHE
3	Controlled Copy	QC
4	Controlled Copy	MP
5	Controlled Copy	WH
6	Controlled Copy	R & D
7	Controlled Copy	PG

SECTION 18: REVISION HISTORY

Rev. No.	Reason for review	Effective Date
00	Fresh Issue	30.05.2014
01	Storage condition Updated Melting point Updated	09.08.2014
02	Storage Temperature Condition updated	20.10.2014
03	Storage Temperature and Packaging condition updated	02.12.2015
04	Periodic Review	01.12.2018

	Prepared by	Checked by	Approved by
Signature			
Date	23/11/2018	23/11/2018	
Name	Mr. Narasimha N	Mr. Kannan R.S.	Mr. Venkatesh S. Rao
Designation	Officer-RHS	HOD-Safety	HOD-QA

MASTER COPY
DATE
01 DEC 2018



DATE OF NEXT REVIEW
01
23 DEC 2020



Srikem Laboratories Pvt. Limited, 17/24, MIDC Talaja,
Navi Mumbai, Maharashtra (India)

MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Product : PERMETHRIN (PHARMA GRADE)
Synonyms : (3-2, 2Dichlorophenyl-2, 2 Dimethylcyclopropanecarboxylic
Acid 3phenoxyphenyl methyl ester)-
Company Identification : M/s. Srikem Laboratories Pvt. Ltd.
Address : 17/24, M.I.D.C. Talaja,
Navi Mumbai - 410 208.

2. COMPOSITION / INFORMATION ON INGREDIENTS

CAS# : [52645-53-1]

Molecular Formula : $C_{21}H_{29}Cl_2O_3$

3. HAZARD INFORMATION

None : Caution- Keep out of reach of Children.

4. FIRST AID MEASURES

Ingestion : Wash out mouth with copious amounts of water for
At least 15 minutes. Seek Medical Attention.
Inhalation : Remove to fresh air, rest and keep warm. In severe cases
Or if symptoms persists, Seek Medical attention.
Skin Contact : Immediately wash skin with copious amounts of water for
at least 15 minutes while removing contaminated clothing
and shoes. If irritation persists, Seek medical attention.
Eye Contact : Immediately flush the eyes with copious amounts of water
for at least 15 minutes. Ensure adequate flushing by
separating the eyelids with fingers. If irritations persists,
seek medical advice.

5. FIRE FIGHTING MEASURES

Extinguishing media : Water spray, Carbon dioxide, dry chemical powder or
Appropriate foam.
Special Firefighting : Wear self-contained breathing apparatus and
procedures : protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Wear disposable
coverlets and discard them after use. Sweep up, place in a bag and hold for waste disposal. Avoid
raising dust. Ventilate area and wash spill site after material pickup is complete. Evacuate area.

7. HANDLING AND STORAGE

Refer to section 8

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Use only in a chemical fume hood. Safety shower and eye bath. Wash contaminated clothing
before reuse. Wash thoroughly after handling. Do not breathe dust. Do not get in eyes, on skin, on
clothing. Avoid prolonged or repeated exposure.
NIOSH/MSHA, EU CEN - approved respirator.
Compatible chemical-resistant gloves. Chemical safety goggles. Store in close and tight container
at cool dry place. Keep out of reach of Children.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and odor : Appearance- yellow, brown liquid
Flash Point- not applicable

10. STABILITY AND REACTIVITY

Stability : Stable.
Incompatibilities : Strong oxidizing agents





Srikem Laboratories Pvt. Limited, 17/24, MIDC Taloja,
Navi Mumbai, Maharashtra (India)

MATERIAL SAFETY DATA SHEET

Hazardous combustion or Carbon monoxide, carbon dioxide, nitrogen oxides,
Decomposition products: hydrogen gas.
Hazardous polymerization : Will not occur.

11. TOXICOLOGICAL INFORMATION

Acute effects. May be harmful by inhalation, ingestion or skin absorption. May cause eye irritation, may cause skin irritation. Material may be irritating to mucus membranes and upper respiratory tract. The toxicological properties have not been thoroughly investigated. May cause extra pyramidal reactions.

12. ECOLOGICAL INFORMATION

Data not yet available.

13. DISPOSAL CONSIDERATIONS

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

14. TRANSPORT INFORMATION

Safe to transport by air, sea, surface. (non Regulated)

15. REGULATORY INFORMATION

European information Harmful.

R 63 Possible risk of harm to the unborn child.

R 62 Possible risk of impaired fertility.

S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36 Wear suitable protective clothing.

16. TOXICITY DATA

(The meaning of any abbreviations which appear in this section is given below)

Note : Toxicity depends on cis-trans ratio of the products.

ORL-RAT LD50 430 - 4000 mg Kg⁻¹

ORL-MUS LD50 540 - 2700 mg Kg⁻¹

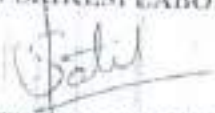
SKN-RAT LD50 > 4000 mg Kg⁻¹

SKN-RBT LD50 > 2000 mg Kg⁻¹

17. OTHER INFORMATION

This information is accurate to the best of our knowledge and the information obtained from sources believed to be accurate. We do not assume any legal responsibility or warranty for its use.

For SRIKEM LABORATORIES PVT. LTD.


AUTHORISED SIGNATORY



MATERIAL SAFETY DATA SHEET

1. Product Identification

Name : Clotrimazole
CAS Registry Number : [23593-75-1]
Manufacturer : Stride Industries
Manufacturer Address : Plot No. 7613/1,
Near Karmatur cross road,
Industrial Estate, GIDC,
Ankleshwar- 393002.
State: Gujarat, India.

2. Composition, Information or Ingredients

Component	CAS No	Weight %
1H-Imidazole, 1-[(2-chlorophenyl)diphenylmethyl]	[23593-75-1]	>95

Clotrimazole is used to treat skin infections such as athlete's foot, jock itch, ringworm, and other fungal skin infections (candidiasis). This medication is also used to treat a skin condition known as pityriasis (tinea versicolor), a fungal infection that causes a lightening or darkening of the skin of the neck, chest, arms, or legs. Clotrimazole is an azole antifungal that works by preventing the growth of fungus.

3. Hazard Identification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute oral toxicity	Category 4
Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 2

Label Elements



GHS Hazard Phrases

: The substance is classified and labelled according to the CLP regulation
: H302 Harmful if swallowed.
Harmful to aquatic life with long lasting effects.

GHS Precaution Phrases:

: Avoid release to the environment.



P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P330 Rinse mouth.
P501 Dispose of contents/container in accordance with local/ regional /national/ international regulations.

4. First Aid Measures

Eye Contact	: Rinse opened eye for several minutes under running water.
Skin Contact	: Immediately wash with water and soap and rinse thoroughly.
Inhalation	: Supply fresh air; consult doctor in case of complaints
After swallowing	: Do not induce vomiting.

5. Fire-Fighting Measures

Extinguishing media	: CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Special hazards arising from the substance or mixture	: Formation of toxic gases is possible during heating or in case of fire.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	: Wear protective clothing
For emergency responders	: No additional information available
Environmental precautions	: Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/ surface or ground water.
Methods and material for containment and cleaning up:	: Dispose of contaminated material as waste according to item 13..

7. Handling and Storage

Precautions for safe handling:	: Store in cool, dry place in tightly closed receptacles.
Information about fire - and explosion protection	: No special measures required
Requirements to be met by storerooms and receptacles:	: Store in a cool location. Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle. Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
Information about storage in one common storage facility:	: Store away from foodstuffs.
Further information about storage conditions:	: None.
Specific end use(s)	: No further relevant information available.

8. Exposure Controls and Personal Protection

Ingredients with limit values that require monitoring at the workplace	: Not required.
General protective and hygienic measures:	: Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.
Hand protection	: The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Eye protection	: Safety glasses
Respiratory protection	: Not required.

9. Physical and Chemical Properties:

Description	: A white or pale yellow, crystalline powder.

Solubility	: Freely soluble in acetone, in chloroform, alcohol, in methanol. Practically insoluble in water.
Melting range	: 141-145°C
pKa values	: No data available
Partition Co-efficient n-octanol/water (log value): (Log p)	: 6.2 (TOXNET)

10. Stability and Reactivity

Reactivity	: Stable under normal conditions
Chemical stability	: Stable under normal conditions
Possibility of hazardous reaction	: No dangerous reactions known
Conditions to avoid	: Heat, Moisture, Air.
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: Formation of toxic gases is possible during heating or in case of fire.

11. Toxicological Information

Toxicity	: Acute toxicity: Oral LD50: LD50 = 708 mg/kg (Rat)
Skin corrosion/irritation	: No irritating effect
Serious eye damage/irritation	: No irritating effect
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Sensitization:	: No sensitizing effects known.

12. Ecological Information

Mobility	: Data no available
Degradability	: Data no available
Cumulative potential	: Data no available
Other adverse effects	: Data no available

13. Disposal Considerations

Waste treatment methods	: Must not be disposed of together with household garbage. Do not allow product to reach sewage system

14. Transport Information

No supplementary information available

15. Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

- Philippines Inventory of Chemicals and Chemical Substances Substance is not listed.
- Australian Inventory of Chemical Substances Substance is not listed.
- Standard for the Uniform Scheduling of Drugs and Poisons Substance is not listed.
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16. Other Information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide.

**MATERIAL SAFETY DATA SHEET
PERMETHRIN**

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Section 1. Identification of the Substance/Mixture and of the Company/ Undertaking

- 1.1 Product Code : PMT
Product Name : Permethrin
Synonyms : (3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate

- 1.2 Relevant identified uses of the substance or mixture and uses advised against:
For use as recommended by the label.

- 1.3 Details of the Supplier of the Safety Data Sheet:

Company Name : AARIVA PHARMA PRIVATE LIMITED
Factory Address : Survey No.809, Mevli Road, Samliya, Ta.-Savli, Dist. Vadodra 391520
Web site address : aarivapharma1@gmail.com

Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture:

Acute Toxicity-Inhalation (Dust/Mist) Category 4
Acute Toxicity-Oral Category 4
Skin Sensitization Category 1
Aquatic Toxicity (Acute) Category 1
Aquatic Toxicity (Chronic) Category 1

- 2.2 Label Elements:

GHS label elements

The substance is classified and labelled according to the Globally Harmonized System

Hazard Pictogram



Signal word Warning

GHS Hazard Phrases:

H302 Harmful if swallowed
H317 May cause an allergic skin reaction

**MATERIAL SAFETY DATA SHEET
PERMETHRIN**

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- H332 : Harmful if inhaled.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

GHS Precaution Phrases:

- P261 : Avoid breathing (dust/fume/gas/mist/vapours/spray).
P264 : Wash (hands) thoroughly after handling.
P272 : Contaminated work clothing should not be allowed out of the workplace.
P273 : Avoid release to the environment.
P280 : Wear (protective gloves/protective clothing/eye protection/face protection).

GHS Response Phrases:

- P301+312: If Swallowed.
P312 : Call a Poison Centre or doctor/physician if you feel unwell.
P302+352: IF ON SKIN: Wash with plenty of soap and water.
P304+340: IF (INHALED): Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P330 : Rinse mouth.
P333+313: If skin irritation or rash occurs, seek medical advice/attention.
P362+364: Take off contaminated clothing and wash it before reuse.
P391 : Collect spillage.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.3 Adverse Human Health Effects and Symptoms:

- Harmful if inhaled or swallowed.
Material may be irritating to the mucous membranes and upper respiratory tract.
May be harmful by skin absorption.
May cause an allergic skin reaction.
May cause eye, skin, or respiratory system irritation.
Very toxic to aquatic life with long lasting effects.
To the best of our knowledge, the toxicological properties have not been thoroughly investigated.



MATERIAL SAFETY DATA SHEET PERMETHRIN

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Section 3. Composition/Information on Ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name) / REACH Registration No.	Concen- tration	EC No./ EC Index No.	GHS Classification
52645-53-1/ GZ1255000	Permethrin	100.0 %	258-067-9 613-058-00-2	Acute Tox. (O) 4 H302 Skin Sens. 1 H317 Acute Tox. (I) 4 H332 Aquatic (A) 1 H400 Aquatic (C) 1 H410

Section 4. First Aid Measures

Description of First Aid Measures:

In Case of Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In Case of Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire Fighting Measures

5.1 Suitable Extinguishing Media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.

Use water spray to cool fire-exposed containers

Unsuitable Extinguishing Media: A solid water stream may be inefficient.

5.2 Flammable Properties and Hazards : No data available.

Flash Point : No data available.

Explosive Limits : LEL: No data available.

UEL: No data available.



**MATERIAL SAFETY DATA SHEET
PERMETHRIN**

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Auto-ignition Point : No data available.

- 5.3 Fire Fighting Instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

6.1 Protective Precautions, Protective Equipment and Emergency Procedure:

Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Precautions:

Take steps to avoid release into the environment, if safe to do so.

6.3 Methods and Material for Containment and Cleaning Up:

Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7. Handling and Storage

7.1 Precautions to Be Taken in Handling:

Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid prolonged or repeated exposure.

7.2 Precautions to Be Taken in Storing:

Keep container tightly closed. Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters : No data available

8.2 Exposure Controls:

8.2.1 Engineering Controls (Ventilation etc.): Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:

Eye Protection : Safety glasses



MATERIAL SAFETY DATA SHEET PERMETHRIN

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Protective Gloves : Compatible chemical-resistant gloves

Other Protective Clothing : Lab coat

Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

Work/Hygienic : Do not take internally.

Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.
Wash thoroughly after handling.

Maintenance Practices: No data available.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Physical States : ☐ Gas ☐ Liquid ☒ Solid

Appearance and Odor : A crystalline solid

pH : No data available

Melting Point : No data available

Boiling Point : No data available

Flash Point : No data available.

Evaporation Rate : No data available.

Flammability (Liquid, gas) : No data available.

Explosive Limits : LEL: No data available.

UEL: No data available.

Vapor Pressure (vs. Air or mm Hg): No data available.

Vapor Density (vs. Air = 1) : No data available.

Specific Gravity (Water = 1) : No data available.

Solubility in Water : No data available.

Solubility Notes : ~14 mg/ml in EtOH, ~18 mg/ml in DMSO;

~33 mg/ml in DMF;

Octanol/Water Partition : No data available.



MATERIAL SAFETY DATA SHEET
PERMETHRIN

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Coefficient Autoignition Point : No data available.

Decomposition Temperature : No data available.

Viscosity : No data available.

9.2 Other Information

Percent Volatile : No data available.

Molecular Formula & Weight : $C_{21}H_{20}Cl_2O_3$ & 391.3

Section 10. Stability and Reactivity

10.1 Reactivity : No data available.

10.2 Stability : Unstable [] Stable [X]

10.3 Stability Note(s) : Stable if stored in accordance with information.

10.4 Polymerization : Will occur [] Will not occur [X]

10.5 Conditions to Avoid : No data available.

10.6 Incompatibility – Materials to Avoid : Strong oxidizing agents

10.7 Hazardous Decomposition of by-products : Carbon dioxide, carbon monoxide,
hydrogen chloride gas

Section 11. Toxicological Information

11.1 Information on Toxicological Effects:

Oral, Dermal and Inhalation hazards (Dust/Mist)

Oral Toxicity LD ₅₀ (rat)	Dermal Toxicity LD ₅₀ (rabbit)	Inhalation Toxicity by Dusts and Mists LC ₅₀ (rat)
275 mg/kg	750 mg/kg	3 mg/L

Section 12. Ecological Information

12.1 Toxicity : Avoid release into the environment.

Runoff from fire control or dilution water may cause pollution.

12.2 Persistence and Degradability : No data available.

12.3 Bio-accumulative Potential : No data available.

12.4 Mobility in Soil : No data available.

12.5 Results of PBT and vPvB assessment: No data available.





MATERIAL SAFETY DATA SHEET PERMETHRIN

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Permethrin	CAA HAP, ODC: No, CWA NPDES: No, TSCA: No, CA PROP 65: No
Regulatory Information 1910.1200 and Regulation (EC)	: This SDS was prepared in accordance with 29 CFR

Section 16. Other Information

Additional information about this product: No data available.

Company Policy or Disclaimer:

This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.



SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Tacrolimus
CAS-No : 109581-93-3

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : JOYANG LABORATORIES
NO 9,HAIDU NORTH ROAD, SHEYANG ECONOMIC
DEVELOPMENT ZONE, YANCHENG, JIANGSU, 224300
CHINA

1.4 Emergency telephone number

Emergency Phone # : +86 515 86319898

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Acute toxicity, Oral (Category 3), H301

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram



Signal word

Danger

Hazard statement(s)

H301

Toxic if swallowed.

Precautionary statement(s)

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER/doctor.

Supplemental Hazard
Statements

none

2.3 Other hazards - none

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms	: FK-506 monohydrate
Formula	: $C_{44}H_{69}NO_{12} \cdot H_2O$
Molecular weight	: 822.03 g/mol
CAS-No.	: 109581-93-3

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component		Classification	Concentration
Tacrolimus			
CAS-No.	109581-93-3	Acute Tox. 3, H301	$\leq 100\%$

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x)

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Preserve in tight containers. Store at temperature less than 25°

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personal protective equipment

Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 186(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatri® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatrill® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use (EN 143) respirator cartridges as a backup to engineering controls. If th full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance	Form: powder
b) Odour	No data available
c) Odour Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	No data available
f) Initial boiling point and boiling range	No data available
g) Flash point	No data available
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapour pressure	No data available
l) Vapour density	No data available
m) Relative density	No data available
n) Water solubility	No data available
o) Partition coefficient, n-octanol/water	No data available
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available

9.2 Other safety information
No data available

SECTION 10: Stability and reactivity

- 10.1 Reactivity**
No data available
- 10.2 Chemical stability**
Stable under recommended storage conditions.
- 10.3 Possibility of hazardous reactions**
No data available
- 10.4 Conditions to avoid**
No data available
- 10.5 Incompatible materials**
Strong oxidizing agents
- 10.6 Hazardous decomposition products**
Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx)
Other decomposition products - No data available
In the event of fire: see section 5
-

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 134 mg/kg(Tacrolimus)

Skin corrosion/irritation

No data available(Tacrolimus)

Serious eye damage/eye irritation

No data available(Tacrolimus)

Respiratory or skin sensitisation

No data available(Tacrolimus)

Germ cell mutagenicity

No data available(Tacrolimus)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Tacrolimus)

Specific target organ toxicity - single exposure

No data available(Tacrolimus)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Tacrolimus)

Additional Information

RTECS: KD4201200

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.(Tacrolimus)

12.1	Toxicity No data available
12.2	Persistence and degradability No data available

No data available

No data available

No data available

No data available (Tacrolimus)

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

No data available

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chem scrubber.

Contaminated packaging

Dispose of as unused product

14.1 UN number

ADR/RID: -

IMDG -

IATA: -

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

ADP/RID:-

IMDG: -

IATA: -

ADR/RID:-

IMDG:

IATA: =

ADR/RID: 00

IMDG Marine pollutant: no

LATA: no

No data available

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

For this product a chemical safety assessment was not carried out

Full text of H-Statements referred to under sections 2 and 3.

H301	Toxic if swallowed

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Identification:

Name: DIOCTAHEDRAL SMECTITE

Company Identification :

HANGZHOU ZHONGBAO IMP AND EXP CORP., LTD.

SECTION 2 - COMPOSITION, INFORMATION ON INGREDIENTS

CAS #	Chemical Name	EINECS #
1318-93-0	DIOCTAHEDRAL SMECTITE	unlisted

Hazard Symbols: None Listed.

Risk Phrases: None Listed.

SECTION 3 - HAZARDS IDENTIFICATION

The toxicological properties of this material have not been fully investigated. May cause eye and skin irritation; May cause respiratory and digestive tract irritation. Target Organs: None.

Potential Health Effects

Eye: Dust may cause mechanical irritation.

Skin: May cause skin irritation.

Ingestion: May cause gastrointestinal irritation with nausea, vomiting and diarrhea. The toxicological properties of this substance have not been fully investigated.

Inhalation: Dust is irritating to the respiratory tract. The toxicological properties of this substance have not been fully investigated.

Chronic: No information found.

SECTION 4 - FIRST AID MEASURES

Eyes: Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid immediately.

Skin: Get medical aid. Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse.

Ingestion: If victim is conscious and alert, give 2-4 cupfuls of milk or water. Never give anything by mouth to an unconscious person. Get medical aid immediately.

Inhalation: Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.

SECTION 5 - FIRE FIGHTING MEASURES

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Substance is noncombustible.

Extinguishing Media: Use water spray, dry chemical, carbon dioxide, or appropriate foam.

Autoignition Temperature: Not available.

Flash Point: Not available.

Explosion Limits: Not available.

Explosion Limits: Not available.

NFPA Rating: health: 1; flammability: 0; instability: 0.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks: Clean up spills immediately, observing precautions in the Protective Equipment section. Sweep up or absorb material, then place into a suitable clean, dry, closed container for disposal. Avoid generating dusty conditions. Provide ventilation.

SECTION 7 - HANDLING AND STORAGE

Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Minimize dust generation and accumulation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation.

Storage: Store in a tightly closed container. Store in a cool, dry, well-ventilated area away from incompatible substances.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls: Use adequate ventilation to keep airborne concentrations low.

Exposure Limits

Personal Protective Equipment

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin: Wear appropriate protective gloves to prevent skin exposure.

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respirators: Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are

exceeded or if irritation or other symptoms are experienced.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State: White to gray white powder

Odor: None reported

PH: Not available

Vapor Pressure: Not available

Vapor Density: Not available

Evaporation Rate: Not available

Viscosity: Not available

Boiling Point: Not available

Freezing/Melting Point: Not available

Decomposition Temperature: Not available

Solubility in water: Not available

Specific Gravity/Density:

Molecular Formula: Not applicable

SECTION 10 - STABILITY AND REACTIVITY

Chemical Stability: Stability unknown

Conditions to Avoid: Incompatible materials, dust generation, strong oxidants

Incompatibilities with Other Materials: Not available

Hazardous Decomposition Products: Strong oxidants

Hazardous Polymerization: Has not been reported

SECTION 11 - TOXICOLOGICAL INFORMATION

RTECS#: CAS# 1318-93-0: None listed

LD50/LC50: RTECS: Not available

Carcinogenicity: This product not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65

SECTION 12 - ECOLOGICAL INFORMATION

Other: No information available.

SECTION 13 - DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with federal, state, and local regulations.

SECTION 14 - TRANSPORT INFORMATION

US DOT

- No information available.

Canadian TDG

- No information available.

SECTION 15 - REGULATORY INFORMATION

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols: Not available

Risk Phrases:

Safety Phrases:

S 24/25 Avoid contact with skin and eyes.

S 28A After contact with skin, wash immediately with plenty of water.

S 37 Wear suitable gloves.

S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

WGK (Water Danger/Protection)

CAS# 1318-93-0: Not available

Canada

CAS# 1318-93-0 is listed on Canada's DSL List

Canadian WHMIS Classifications: Not available

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.

CAS# 1318-93-0 is not listed on Canada's Ingredient Disclosure List.

US Federal

TSCA

CAS# 1318-93-0 is not listed on the TSCA Inventory. It is for research and development use only.

SECTION 16 - ADDITIONAL INFORMATION

MSDS Creation Date: 03/06/2019

Revision #2 Date 02/07/2022

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages.



PREDNICARBATE

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING	
1.1 Product Identifier	
Substance Name	Prednicarbate
CAS-No	73771-04-7
EC-No.	277-590-3
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Identified Uses	Laboratory chemicals, Manufacture of substances
1.3 Details of supplier of safety data sheet	
Company	Symbiotica Speciality Ingredients Sdn. Bhd.
Address	13, Lorong Perusahaan Sungai Lokan 2, Taman Industri Sungai Lokan, 13800, Butterworth, Pulau Pinang, Malaysia
Telephone	+604-5189000
Fax	+604-3581700
E-mail Address	symbioti@symbiotica.com.my
1.4 Emergency telephone number	
Emergency Phone	+604-5189000

2. HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Classification according to Regulation (EC) No 1272/2008 (CLP) Repr.2 & STOT RE 2	
2.2 Label elements	
Classification according to Regulation (EC) No 1272/2008 (CLP) Hazard pictograms: GHS08: Health hazard	
	
Signal Word Warning	
Hazards statement(s) H360: May damage the unborn child. H373: Causes damage to organs.	
Precautionary statement(s) P260: Do not breathe dust. P281: Use personal protective equipment as required. P314: Get medical advice/attention if you feel unwell.	
2.3 Other hazards None	

3. COMPOSITION / INFORMATION ON INGREDIENTS	
3.1 Substances	
Chemical Name	2-(17-ethoxycarbonyloxy-11-hydroxy-10,13-dimethyl-3-oxo-7,8,9,11,12,14,15,16-octahydro-6h-cyclopenta[a]phenanthren-17-yl)-2-oxo-ethyl propanoate
Synonyms	*Prednicarbatum

<i>Formula</i>	C ₁₂ H ₁₆ O ₄
<i>Molecular Weight</i>	488.57 g/mol
<i>Classification</i>	Repr.2; H360 & STOT RE 2;H373

4. FIRST AID MEASURES

4.1 Description of first aid measures

<i>General Advice</i>	Consult a physician. Show this safety data sheet to the doctor in attendance.
<i>If Inhaled</i>	Assure fresh air breathing. If you feel unwell, seek medical advice
<i>In Case of Skin Contact</i>	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
<i>In Case of eye contact</i>	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persists.
<i>If Swallowed</i>	Rinse mouth .If swallowed, seek medical advice immediately and show this container or label.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after ingestion: Symptoms may include dizziness, headache, nausea and loss of coordination

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent, Pharmaceutical.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

<i>Suitable extinguishing media</i>	Water spray, carbon dioxide and dry powder.
<i>Unsuitable extinguishing media</i>	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

<i>Vapor</i>	Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

5.3 Advice for firefighters

<i>Special protective equipment for fire-fighters</i>	Wear self contained breathing apparatus for fire fighting if necessary. Avoid (reject) fire-fighting water to enter environment. Prevent entry to sewers and public waters

6. ACCIDENTAL RELEASE MEASURES

<i>General</i>	Remove ignition sources. Evacuate area.

6.1 Personal precautions, protective equipment and emergency procedures

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environment precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3 Methods and materials for containment and cleaning up

Clean spills promptly. To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation.

6.4 Reference to other sections

For disposal refer section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in 15°C to 30°C place. Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

No data available

8.2 Exposure controls

Appropriate engineering control

Keep in a well-ventilated room. Use only in an exhaust booth with integrated air filter, High efficiency particulate air filter (HEPA filter).

Personal Protective Equipment

<i>Respiratory protection</i>	Wear approved mask (P3). In case of insufficient ventilation, wear suitable respiratory equipment.
<i>Hand protection</i>	Chemically resistant protective gloves.
<i>Eye protection</i>	Chemical goggles or safety glasses.
<i>Skin and body protection</i>	Use chemically protective clothing.
<i>Hygiene measures</i>	Provide local exhaust or general room ventilation. Material should be handled in a laboratory hood whenever possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<i>Appearance</i>	White to almost white crystalline powder
<i>Melting Point</i>	Melts at about - 110°C to 112°C
<i>Solubility</i>	Water - Practically Insoluble Acetone - Freely Soluble Alcohol - Freely Soluble Propylene Glycol - Sparingly Soluble

9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical Stability

Stable.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Heat, Direct sunlight.

10.5 Incompatible materials

Strong oxidizers.

10.6 Hazardous decomposition products

Carbon dioxide, Hydrogen fluoride, Carbon monoxide, Chlorides, When heated to decomposition, emits dangerous fumes.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

<i>Acute toxicity</i>	No data Available
<i>Carcinogenicity</i>	No data Available
<i>Chronic toxicity</i>	No data Available
<i>Reproductive toxicity</i>	Category 2: Suspected of damaging fertility or the unborn child.
<i>Additional Information</i>	No data Available

12. ECOLOGICAL INFORMATION

12.1 Toxicity	General: Hazardous waste. Use suitable disposal containers.
12.2 Persistence and degradability	No data available
12.3 Bioaccumulative potential	No data available
12.4 Mobility in Soil	No data available
12.5 PBT and vPvB assessment	No data available
12.6 Other adverse effects	No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product	Observe all federal, state and local environmental regulations. This product contains hazardous components for the environment. Avoid release to the environment.
Contaminated packaging	Dispose its container at hazardous or special waste collection point.

14. TRANSPORTATION

14.1 UN number	No data available
14.2 UN proper shipping name	
ADR/RID	Not dangerous goods.
IMDG	Not dangerous goods.
IATA	Not dangerous goods.
14.3 Transport Hazard Class(es)	Not applicable
14.4 Packaging group	Not applicable
14.5 Environmental hazards	No hazard identified
14.6 Special precaution for user	No data available

15. REGULATORY INFORMATION

Labeling according to EC Directives.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available

15.2 Chemical safety assessment

No data available

16. OTHER INFORMATION

Indication of changes: all the sections are updated according to ECHA Guidance

Abbreviations and acronyms:

a.	CAS NO	:	Chemical abstracts service number
b.	EC	:	European Commission
c.	CLP	:	Classification Labelling And Packaging Regulation
d.	STOT	:	Specific target organ toxicity
e.	RTECS	:	Registry of Toxic Effects of Chemical Substances
f.	ECHA	:	European Chemicals Agency
g.	PBT	:	Persistent, Bioaccumulative and Toxic
h.	vPvB	:	very Persistent and very Bioaccumulative

Additional information:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the mentioned product, storage, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other product or in the case of processing, the information the material safety data sheet is not necessarily valid for the new made-up material.

SAFETY DATA SHEET

1. Identification

Product Identifier dl- α -Tocopheryl Acetate

Recommended Use: Food additive, cosmetic ingredient

Manufacturer Information:

Company Name: Zhejiang Medicine Co., Ltd., Xinchang Pharmaceutical Factory

Address: 98 East Xinchang Dadao Road, Xinchang, Zhejiang, P. R. China

Telephone: +86-575-86126688

Fax: +86-575-86131771

E-mail: zmcteco@xcpharma.com

Emergency phone number: +86-575-86022860

2. Hazards identification

Hazard Classification Not classified

Label elements The product does not require a hazard warning label

Hazards not otherwise classified High risk of slipping due to leakage/spillage of product. The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

3. Composition/information on ingredients

Chemical Name:	CAS No.	Concentration (w/w)*
dl- α -Tocopheryl Acetate	7695-91-2	100%

Remarks: *The data is based on average.

4. First-aid measures

Description of first aid measures

Inhalation: Remove to fresh air, call a physician if necessary.

Skin contact: Remove contaminated clothes. Wash thoroughly with soap & water. If irritation develops, seek medical attention.

Eye contact: Wash affected eyes for at least 15 minutes under running water with eyelids held open. If irritation develops, seek medical attention.

Ingestion: Rinse mouth and then drink plenty of water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Symptoms: No specific symptoms known

Indication of any immediate medical attention and special treatment needed

Note to physicians: Treat symptomatically

5. Fire-fighting measures

Extinguishing media

Suitable Extinguishing media: Water spray, carbon dioxide, foam, dry extinguishing media.

Unsuitable Extinguishing media: None known

Special hazards arising from the substance or mixture

Hazard during fire-fighting: Carbon oxides, harmful vapours.

Special protective equipment or precautions for firefighters

Firefighters should be equipped with self-contained breathing apparatus and turn-out gear.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear suitable protective clothing.

Environment precautions: Do not discharge into drains/surface water/groundwater.

Methods and material for containment and cleaning up

Pick up spilled material and containerize for recovery or disposal.

7. Handling and storage

Precautions for safe handling: Ensure adequate ventilation.

Conditions for safe storage, including any incompatibilities: Keep container tightly sealed. Protect contents from light, humidity, and heat.

8. Exposure controls/personal protection

Occupational exposure limits: Not exposure limits value known.

Appropriate engineering controls	Provide local exhaust ventilation to control vapours.
Personal protective measures	
Eye/face protection:	Safety glasses with side-shields.
Skin and body protection	Protection must be chosen based on level of activity and exposure.
Respiratory protection	No personal respiratory protective equipment normally required. Wear respiratory protection if ventilation is inadequate.
General safety and hygiene measures:	Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Wash soiled clothing immediately.

9. Physical and chemical properties

Physical state:	A clear, yellow or slightly greenish-yellow viscous oily liquid
Color:	Clear, yellow or slightly greenish-yellow
Odor:	Odorless
Odor threshold:	Not available
pH:	Not applicable
Boiling point:	>300 °C
Initial boiling point and boiling range:	Not applicable
Flash point:	Approx. 280 °C
Evaporation rate:	Not applicable
Flammability:	Not highly flammable
Upper/Lower flammability or explosive limits:	Not available
Vapor pressure:	Approx. 1.4 mbar (approx. 240°C) Approx. 4.0 mbar (approx. 270°C)
Vapor density:	Not applicable
Density:	0.95-0.96 g/cm ³ (approx. 20°C)
Water solubility:	Insoluble
Auto-ignition temperature:	303 °C
Decomposition temperature:	Not available

10. Stability and reactivity

Reactivity:	No hazardous reactions if stored and handled as indicated.
Chemical stability:	The product is stable if stored and handled as indicated.

Possibility of hazardous reactions:	None if used for intended purpose.
Conditions to avoid:	Avoid direct sunlight. Avoid heat.
Incompatible materials:	Strong acids and strong bases. Strong oxidizing agents
Hazardous decomposition products:	No hazardous decomposition products if stored and handled as indicated

11. Toxicological information

Information on the likely routes of exposure:	Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.
Acute toxicity:	LD ₅₀ > 10,000mg/kg (oral, rat)
Irritation/corrosion:	Non-irritant
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Sensitisation:	Non-Sensitizing
Mutagenicity:	No data available.
Carcinogenicity:	No data available.
Reproduction toxicity:	No data available.
Symptoms of Exposure:	No data available.

12. Ecological information

Ecotoxicity:	Quantitative data on the ecologic effect of this product are not available.
Persistence and degradability:	Inherently biodegradable.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.

13. Disposal considerations

Waste disposal of substance:	Do not discharge into waterways or sewer systems without proper authorization. Dispose of in accordance with national, state and local regulations.
Container disposal:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

Land transport:	Not classified as a dangerous good under transport regulations
Sea transport	Not classified as a dangerous good under transport regulations
Air transport	Not classified as a dangerous good under transport regulations

15. Regulation Information

Regulation Information	In according with Regulation (EC) No 1272/2008 and 29 CFR part 1910.1200

16. Other information

Revised date: 01-September -2019

Version #: 010

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

HEBEI DONGFENG PHARMACEUTICAL CO., LTD.

DOXYCYCLINE HYCLATE

MATERIAL SAFETY DATA SHEET

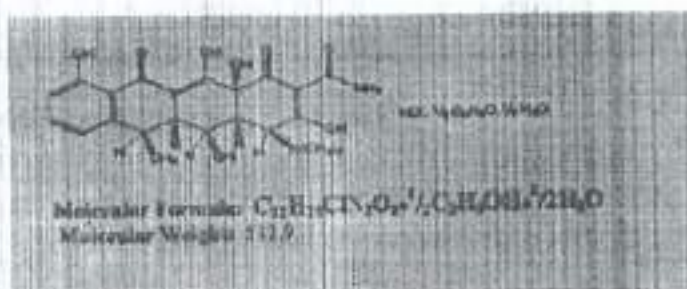
Section 1 - Product and Company Information

Product Name DOXYCYCLINE HYCLATE
 Manufacturer HEBEI DONGFENG PHARMACEUTICAL CO., LTD.
 Address No. 365, Guangyuan West Street, Yongnian district, Handan City, Hebei, P.R. CHINA
 Telephone: ++86 310 6805222
 Fax: ++86 310 6806299

Section 2 - Composition/Information on Ingredient

Substance Name DOXYCYCLINE HYCLATE

CHEMICAL STRUCTURE:



DOXYCYCLINE HYCLATE

MOLECULAR FORMULA: $C_{22}H_{25}ClN_2O_8 \cdot \frac{1}{2}C_2H_4O_3 \cdot 2H_2O$

MOLECULAR WEIGHT: 512.9

CAS NUMBER: 24360-14-5

CONCENTRATION: 95.0-102.0%

Synonyms Biocamycin * Doxigalumicina * Doxycycline hyclate * Doxycycline hydrochloride *
 Doxy-II * Doxy-tablinen * Ecodox * Hydramycin * Liomycin * Mespafin *
 Midoxin * Nivocilin * Novadox * Retens * Roximycin * Samecin * Tanamicin *
 Tecacin * Tetradox * Vibradox * Vibramycin hyclate * Vibra-tabs

DESCRIPTION: Doxycycline is a broad spectrum antibiotic synthetically derived from oxytetracycline

PACKING: Packed in fiber drum, with net weight: 25kg/drum, gross weight: 28kg/drum

Section 3 - Hazards Identification

EMERGENCY OVERVIEW

Harmful.

Irritating to eyes, respiratory system and skin. Harmful if swallowed.

Calif. Prop. 65 reproductive hazard. Target organ(s): Teeth. Bones.

HMIS RATING

HEALTH: 2*

FLAMMABILITY: 0

REACTIVITY: 1

NFPA RATING

HEALTH: 2

FLAMMABILITY: 0

REACTIVITY: 1

*additional chronic hazards present.

For additional information on toxicity, please refer to Section 11.

Section 4 - First Aid Measures

ORAL EXPOSURE

If swallowed, wash out mouth with water provided person is conscious.

Call a physician.

INHALATION EXPOSURE

If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

DERMAL EXPOSURE

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes.

Call a physician.

EYE EXPOSURE

In case of contact with eyes, flush with copious amounts of water for at least 15 minutes.

Assure adequate flushing by separating the eyelids with fingers. Call a physician.

Obtain medical attention in all cases.

Section 5 - Fire Fighting Measures

FLASH POINT

N/A

AUTOIGNITION TEMP

N/A

FLAMMABILITY

N/A

EXTINGUISHING MEDIA

Suitable: Water spray. Carbon dioxide, dry chemical powder, or appropriate foam.

DOXYCYCLINE HYCLATE -MSDS

FIREFIGHTING

Protective Equipment: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Specific Hazard(s): Emits toxic fumes under fire conditions.

Section 6 - Accidental Release Measures

PROCEDURE TO BE FOLLOWED IN CASE OF LEAK OR SPILL

Evacuate area.

PROCEDURE(S) OF PERSONAL PRECAUTION(S)

Wear respirator, chemical safety goggles, rubber boots, and heavy rubber gloves.

METHODS FOR CLEANING UP

Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

Section 7 - Handling and Storage

HANDLING

User Exposure: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure.

STORAGE

Preserve in tight, light resistant container. Keep it from light, wet.

Section 8 - Exposure Controls / PPE

ENGINEERING CONTROLS

Safety shower and eye bath. Mechanical exhaust required.

PERSONAL PROTECTIVE EQUIPMENT

Respiratory: Government approved respirator.

Hand: Compatible chemical-resistant gloves.

Eye: Chemical safety goggles.

GENERAL HYGIENE MEASURES

Wash thoroughly after handling.

Section 9 - Physical/Chemical Properties

Appearance	Physical State: Solid Color: Yellow Form: Powder, hygroscopic
Property	Value At Temperature or Pressure
Molecular Weight	512.94 AMU
pH	2.0-3.0
BP/SP Range	N/A

DOXYCYCLINE HYCLATE -MSDS

MP/MP Range	N/A
Freezing Point	N/A
Vapor Pressure	N/A
Vapor Density	N/A
Saturated Vapor Conc.	N/A
SG/Density	N/A
Bulk Density	N/A
Odor Threshold	N/A
Volatile %	N/A
VOC Content	N/A
Water Content	1.4%~2.8%
Solvent Content	N/A
Evaporation Rate	N/A
Viscosity	N/A
Surface Tension	N/A
Partition Coefficient	N/A
Decomposition Temp.	N/A
Flash Point	N/A
Explosion Limits	N/A
Flammability	N/A
Autoignition Temp	N/A
Refractive Index	N/A
Optical Rotation	-105~-120
Miscellaneous Data	N/A
Solubility	Insoluble in water, freely soluble in alcohol, practically insoluble in ether. it dissolves in solutions of alkali hydroxides and carbonates

N/A = not available

Section 10 - Stability and Reactivity

STABILITY

Stable: Stable.

Conditions of Instability: May decompose on exposure to light.

Materials to Avoid: Strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous Decomposition Products: Carbon monoxide, Carbon dioxide, Nitrogen oxides.

Hydrogen chloride gas.

HAZARDOUS POLYMERIZATION

Hazardous Polymerization: Will not occur

Section 11 - Toxicological Information

ROUTE OF EXPOSURE

Skin Contact: Causes skin irritation.

Skin Absorption: Harmful if absorbed through skin.

Eye Contact: Causes eye irritation.

Inhalation: Harmful if inhaled. Material is irritating to mucous membranes and upper respiratory tract.

Ingestion: Harmful if swallowed.

TARGET ORGAN(S) OR SYSTEM(S)

Heart. Liver. Teeth. Bones. Nerves.

SIGNS AND SYMPTOMS OF EXPOSURE

Can cause phototoxic reactions, gastrointestinal disturbances, turn teeth yellow and reduce mineralization. Can cause CNS depression. Exposure can cause: Narcotic effect. Damage to the heart.

CHRONIC EXPOSURE - REPRODUCTIVE HAZARD

Result: Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.

Section 12 - Ecological Information

No data available.

Section 13 - Disposal Considerations

APPROPRIATE METHOD OF DISPOSAL OF SUBSTANCE OR PREPARATION

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.

Section 14 - Transport Information

DOT

Proper Shipping Name: None

Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.

IATA

Non-Hazardous for Air Transport: Non-hazardous for air transport.

Section 15 - Regulatory Information

EU ADDITIONAL CLASSIFICATION

Symbol of Danger: Xn

Indication of Danger: Harmful.

R: 22-36/37/38

Risk Statements: Harmful if swallowed. Irritating to eyes, respiratory system and skin.

S: 26

Safety Statements: In case of contact with eyes, rinse immediately with plenty of water and

DOXYCYCLINE HYCLATE -MSDS

seek medical advice.

US CLASSIFICATION AND LABEL TEXT

Indication of Danger: Harmful.

Risk Statements: Harmful if swallowed. Irritating to eyes, respiratory system and skin.

Safety Statements: Do not breathe dust. Wear suitable protective clothing. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

US Statements: Calif. Prop. 65 reproductive hazard.

SAFETY DATA SHEET

1. IDENTIFICATION

Product name: Mupirocin
Product code: M2955
Company: HANGZHOU ZHONGMEIHUADONG PHARMACEUTICAL CO., LTD.

Address: XIANGFU BRIDGE NO.866 MOGANSHAN RD.,HANGZHOU ,ZHEJIANG,CHINA

Responsible Department: Sales Department
Telephone: +86-(0)576-88886877
Fax: +86-(0)5761-88707069
Emergency telephone: 0576-88707066
Revision number: 1

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

PHYSICAL HAZARDS	Not classified
HEALTH HAZARDS	Not classified
ENVIRONMENTAL HAZARDS	Not classified

Label elements

Pictograms or hazard symbols	None
Signal word	No signal word
Hazard statements	None
Precautionary statements	None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance/mixture:	Substance
Components:	Mupirocin
Percent:	>98.0%(T)
CAS RN:	12650-69-0
Chemical Formula:	$C_{20}H_{34}O_5$

4. FIRST AID MEASURES

Inhalation:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.
Skin contact:	Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion:	Get medical advice/attention if you feel unwell. Rinse mouth.
Protection of first-aiders:	A rescuer should wear personal protective equipment, such as rubber gloves and air-tight goggles.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:

Dry chemical, foam, water spray, carbon dioxide.

Precautions for firefighters: Fire-extinguishing work is done from the windward and the suitable fire-extinguishing method according to the surrounding situation is used. Uninvolved persons should evacuate to a safe place. In case of fire in the surroundings: Remove movable containers if safe to do so.

Special protective equipment for firefighters: When extinguishing fire, be sure to wear personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Keep people away from and upwind of spill/leak. Entry to non-involved personnel should be controlled around the leakage area by roping off, etc.

Environmental precautions:

Prevent product from entering drains.

Methods and materials for containment and cleaning up:

Sweep dust to collect it into an airtight container, taking care not to disperse it. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical measures:

Handling is performed in a well ventilated place. Wear suitable protective equipment. Prevent dispersion of dust. Wash hands and face thoroughly after handling.

Use a local exhaust if dust or aerosol will be generated.

Advice on safe handling:

Avoid contact with skin, eyes and clothing.

Conditions for safe storage, including any incompatibilities

Storage conditions:

Keep container tightly closed. Store in a cool and dark place. Store away from incompatible materials such as oxidizing agents.

Packaging material:

Comply with laws.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering controls:

Install a closed system or local exhaust as possible so that workers should not be exposed directly. Also install safety shower and eye bath.

Personal protective equipment

Respiratory protection:

Dust respirator. Follow local and national regulations.

Hand protection:

Protective gloves.

Eye protection:

Safety glasses. A face-shield, if the situation requires.

Skin and body protection:

Protective clothing. Protective boots, if the situation requires.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state (20°C):

Solid

Form:

Crystal - Powder

Colour:

White - Almost white

Odour:

No data available

pH:

No data available

Melting point/freezing point:

78°C

Boiling point/range:

No data available

Flash point:

No data available

Flammability or explosive limits:

Lower:

No data available

Upper:

No data available

Relative density:

No data available

Solubility(ies):

[Water]

No data available

[Other solvents]

No data available

10. STABILITY AND REACTIVITY

Chemical stability:	Stable under proper conditions.
Possibility of hazardous reactions:	No special reactivity has been reported.
Incompatible materials:	Oxidizing agents
Hazardous decomposition products:	Carbon dioxide, Carbon monoxide

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:	ori-rat LD50: 5 g/kg ivn-rat LD50: 1310 mg/kg scu-rat LD50: 5 g/kg
Skin corrosion/irritation:	No data available
Serious eye damage/irritation:	No data available
Germ cell mutagenicity:	No data available
Carcinogenicity:	No data available
IARC =	No data available
NTP =	No data available
Reproductive toxicity:	No data available
RTECS Number:	RA6907000

12. ECOLOGICAL INFORMATION

Ecotoxicity:	
Fish:	No data available
Crustacea:	No data available
Algae:	No data available
Persistence / degradability:	No data available
Bioaccumulative potential(BCF):	No data available
Mobility in soil	
Log Pow:	No data available
Soil adsorption (K _{oc}):	No data available
Henry's Law (PaM ³ /mol):	No data available

13. DISPOSAL CONSIDERATIONS

Recycle to process, if possible. Consult your local regional authorities. You may be able to dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber system. Observe all federal, state and local regulations when disposing of the substance.

14. TRANSPORT INFORMATION

Hazards Class:	Does not correspond to the classification standard of the United Nations
UN-No:	Not listed

15. REGULATORY INFORMATION

Regulations on the Control over Safety of Dangerous Chemicals (State Council announces on January 26, 2002 and revised on February 16, 2011): Safe use and production, the storage of a dangerous chemical, transport, loading and unloading were prescribed.

16. OTHER INFORMATION

The reference company name of written contents

Company: HANGZHOU ZHONGMEIHUADONG PHARMACEUTICAL CO., LTD.

Address: XIANGFU BRIDGE NO.866 MOGANSHAN RD., HANGZHOU, ZHEJIANG, CHINA

Department: Technical Information Department

Emergency telephone: 0576-88707066

Fax: +86-(0)576-88707069

This SDS was prepared sincerely on the basis of the information we could obtained, however, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity. Prior to use, please investigate not only the hazards and toxicity information but also the laws and regulations of the organization, area and country where the products are to be used, which shall be given the first priority.

The products are supposed to be used promptly after purchase in consideration of safety. Some new information or amendments may be added afterwards, if the products are to be used far behind the expected time of use or you have any questions, please feel free to contact us. The stated cautions are for normal handling only. In case of special handling, sufficient care should be taken, in addition to the safety measures suitable for the situation. All chemical products should be treated with the recognition of "having unknown hazards and toxicity", which differ greatly depending on the conditions and handling when in use and/or the conditions and duration of storage. The products must be handled only by those who are familiar with specialized knowledge and have experience or under the guidance of those specialists throughout use from opening to storage and disposal. Safe usage conditions shall be set up on each user's own responsibility.

Material Safety Data Sheet

Page 1 of 5

1. IDENTIFICATION OF THE SUBSTANCE/ PREPARATION AND COMPANY INFORMATION

Supplier: JOYANG LABORATORIES

HAIDU NORTH ROAD, SHEYANG ECONOMIC DEVELOPMENT ZONE JIANGSU, CHINA

Tel No.: 86 515 88319898

Fax No.: 86 515-88319595

2. COMPOSITION/ INFORMATION ON INGREDIENTS

Components	CAS Number	Weight%	ACGIH Exposure Limits:	OSHA Exposure Limits
Sodium Fusidate	751-94-0	90-100%	None	None

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: May cause irritation and/or dermatitis.

Principle routes of exposure: Skin

Inhalation: May cause irritation of respiratory tract

Ingestion: May be harmful if swallowed

Skin contact: May cause allergic skin reaction

Eye contact: Avoid contact with eyes

Statements of hazard MAY CAUSE ALLERGIC SKIN REACTION.

Statement of Spill or leak-ANSI Label Eliminate all ignition sources. Absorb and/or contain spill with inert materials(e.g. sand, vermiculite). Then place in appropriate container. For large spills, use water spray to disperse vapors, flush spill area. Prevent runoff from entering waterways or sewers.

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Inhalation: Move to fresh air. Call a physician immediately.

Skin contact: Rinse immediately with plenty of water and seek medical advice

Ingestion: Do not induce vomiting without medical advice

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Protection of first-aiders: No information available

Medical conditions aggravated by exposure: None known

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:

Use dry chemical, CO2, water spray or "alcohol" foam

Specific hazards:

Burning produces irritant fumes.

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Material Safety Data Sheet

Unusual hazards:	None known
Special protective equipment for firefighters:	As in any fire, wear self-contained breathing apparatus Pressure-demand, MSHA/NIOSH (approved or equivalent) And full protective gear
Specific methods:	Water mist may be used to cool closed containers.
Flash point:	Not determined
Autoignition temperature:	Not determined
NFPA rating:	
NFPA Health:	1
NFPA Flammability:	1
NFPA Reactivity:	0

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Use personal protective equipment.
Environmental precautions:	Prevent product from entering drains.
Methods for cleaning up:	Sweep up and shovel into suitable containers for disposal.

7. HANDLING AND STORAGE

Storage:	
+4°C	
Handling:	Use only in area provided with appropriate exhaust ventilation.
Safe handling advice:	Wear personal protective equipment.
Incompatible products:	Oxidising and spontaneously flammable products

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering measures:	Ensure adequate ventilation.
PERSONAL PROTECTIVE EQUIPMENT	
Respiratory protection:	Breathing apparatus only if aerosol or dust is formed.
Hand protection:	Pvc or other plastic material gloves
Skin and body protection:	Usual safety precautions while handling the product will provide adequate protection against this potential effect.
Eye protection:	Safety glasses with side-shields
Hygiene measures:	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Powder
Formula:	C ₃₁ H ₄₇ O ₆ Na

Material Safety Data Sheet

Molecular weight:	538.7
Melting point/range:	No data available at this time.
Boiling point/range:	No data available at this time.
Density:	No data available
Vapor pressure:	No data available
Evaporation rate:	No data available
Vapor density:	No data available
Solubility (in water):	No data available
Flash point:	Not determined
Autoignition temperature:	Not determined

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	None under normal processing.
Hazardous decomposition products:	Sodium oxides (Na ₂ O)
Materials to avoid:	Strong oxidising agents
Conditions to avoid:	Exposure to air or moisture over prolonged periods.

11. TOXICOLOGICAL INFORMATION

Product Information

Acute toxicity

Components	RTECS Number:	Selected LD50s and LC50s
FUSIDIC ACID SODIUM SALT	LV5775000	Oral LD50 Mouse: >975mg/kg

Chronic toxicity:	Chronic exposure may cause nausea and vomiting, higher exposure causes Unconsciousness.
Local effects:	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.
Specific effects:	May include moderate to severe erythema (redness) and moderate edema (raised skin), nausea, vomiting, headache.
Primary irritation:	No data is available on the product itself.
Carcinogenic effects:	No data is available on the product itself.
Mutagenic effects:	No data is available on the product itself.
Reproductive toxicity:	No data is available on the product itself.

12. ECOLOGICAL INFORMATION

Mobility:	No data available
Bioaccumulation:	No data available

Material Safety Data Sheet

Ecotoxicity effects: No data available
 Aquatic toxicity: May cause long-term adverse effects in the aquatic environment.

Components	U.S.DOT-Appendix B-Marine Pollutan	U.S.DOT-Appendix B-Severe Marine Pollutants	United Kingdom-The Red List:
Fusidic acid sodium salt	Not Listed	Not Listed	Not Listed
Components	Germany VCI(WGK)	World Health Organization (WHO)-Drinking Water	Ecotoxicity-Fish Species Data
Fusidic acid sodium salt	Not Listed	Not Listed	Not Listed
Components	Ecotoxicity-Freshwater Algae Data	Ecotoxicity-Microtox Data	Ecotoxicity-Water Flea Data
Fusidic acid sodium salt	Not Listed	Not Listed	Not Listed
Components	EPA-ATSDR Priority List	EPA-HPV Challenge Program Chemical List	California-Priority Toxic Pollutants
Fusidic acid sodium salt	Not Listed	Not Listed	Not Listed
Components	California-Priority Toxic Pollutants	California-Priority Toxic Pollutants	
Fusidic acid sodium salt	Not Listed	Not Listed	

13. DISPOSAL CONSIDERATIONS

Waste from residues/unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if Unaltered by use, may be disposed of by treatment at a Permitted facility or as advised by your local hazardous Waste regulatory authority. Residue from fires extinguished With this material may be hazardous.

Contaminated packaging: Do not re-use empty containers

14. TRANSPORT INFORMATION

UN/Id No: Not regulated

DOT: Not regulated

Proper shipping name: Not regulated

Components: U.S.DOT-Appendix A Table I-Reportable Quantities

Fusidic acid sodium salt: Not Listed

TDG(Canada):

WHMIS hazard class: Non-controlled

IMDG/IMO

IMDG-Hazard Classifications: Not Applicable

Material Safety Data Sheet

Components	U.S.DOT-Appendix B-Marine Pollutan	U.S.DOT-Appendix B-Severe Marine Pollutants
Fusidic acid sodium salt	Not Listed	Not Listed

IMO-labels:

15. REGULATORY INFORMATION

International Inventories

Components

Fusidic acid sodium salt

Inventory-United States TSCA-Sect.8(b)

Not Listed

Canada DSL Inventory List-

Not Listed

Australia(AICS):

Present

EU EINECS List-

212-030-3;C31H48O6.Na

16. OTHER INFORMATION

None

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee for the product.

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING:

1.1 Product Identifiers

Product Name : EBASTINE
CAS-No. : 90729-43-4

1.2 Relevant identified uses of the substances or mixture and uses advised against

Identified Uses : Active Pharmaceutical Ingredients (API)

1.3 Detail of the supplier of the safety data sheet

Company : BAL PHARMA LIMITED
61-B, Bommasandra Industrial Area
Bangalore - 560 099
INDIA
Telephone : +91 80-41570814/15/16
Fax : +91 80-41570812

1.4 Emergency telephone number

Emergency Phone : +91 80-41570817 (24 Hours/Day, 7 Days/Week)

2. HAZARD IDENTIFICATION

2.1 Label elements

Labeling according Regulation (EC) No. 1272/2008 [CLP]

Pictogram : None

Signal word : None

Hazard statement(s)

H413 : May cause long lasting harmful effects to aquatic life
P273 : Avoid release to the environment.
P501A : Dispose of contents/container in accordance with applicable

Signature	Prepared by <i>G.S. Patil</i>	Checked by <i>Bhramara</i>	Approved by <i>Shiv</i>
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr.G.S.Patil	Mr. Kannan.R.S.	Mr. Venkatesh.S.Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA

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regulations
 Precautionary statements : None
 Supplemental Hazard Statements: None

2.2 Other hazards : None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms : 1-[4-(1,1-Dimethylethyl)phenyl]-4-[4-(diphenylmethoxy)piperidin-1-yl]butan-1-one

Chemical Formula : $C_{27}H_{31}NO_2$

Molecular Weight : 409.67 g/mol

Component : Ebastine ; CAS-No. 90729-43-4 Concentration: 99-100%

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice:

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled:

If breathed in, move person into fresh air. If not breathing, give artificial respiration.
 Consult a Physician

In case of skin contact:

Wash off with soap and plenty of water. Consult a physician

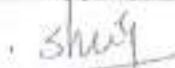
In case of eye contact:

Flush eyes with water as a precaution

If swallowed:

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a Physician

4.2 Most important symptoms and effects, both acute and delayed

Signature	Prepared by	Checked by	Approved by
			
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr. G.S. Patil	Mr. Kannan R.S.	Mr. Venkatesh S. Rao
Designation	Scientist-R&D	HOD-Safety	F. HOD-QA

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To the best of our knowledge the chemical, physical and toxicological properties have not been thoroughly investigated.

4.3 Indication of immediate medical attention and special treatment needed

No data available.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical powder or carbon dioxide.

5.2 Special hazards arising from the substances or mixture

Carbon dioxide, Nitrogen oxides (NOx)

5.3 Precautions for fire-fighters

Wear Self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Method and materials for containment and cleaning up

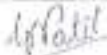
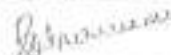
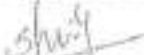
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Signature	Prepared by	Checked by	Approved by
			
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr. G.S. Patil	Mr. Kannan R.S.	Mr. Venkatesh S. Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA
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Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection

7.2 Condition for safe storage, including any incompatibilities

Store at room temperature in a well closed container, protected from light.

7.3 Specific end uses

No data available

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

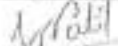
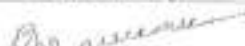
Use equipment (like Goggles, safety glasses, face shields) for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with the product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment (eg. Aprons and gowns, lab coats or jackets) must be selected according to the concentration and amount of the dangerous substance at the specific work place.

Signature	Prepared by	Checked by	Approved by
			
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr.G.S.Patil	Mr. Kannan.R.S.	Mr.Venkatesh.S.Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA

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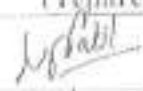
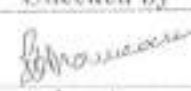
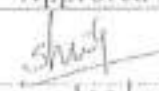
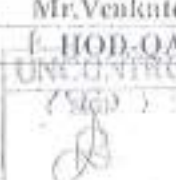
Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95(US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance Form	: White or almost white crystalline powder
b) Odor	: Odorless
c) Odor Threshold	: No data available
d) pH	: No data available
e) Melting/freezing point	: About 86°C
f) Boiling point	: > 300 deg. C
g) Flash point	: No data available
h) Evaporation rate	: No data available
i) Flammability (Solid, gas)	: Flammable when exposed to a source of ignition
j) Upper/Lower flammability or explosive limits	: No data available
k) Vapour pressure	: No data available
l) Vapor density	: No data available
m) Relative density	: No data available
n) Water solubility	: Practically insoluble in water
o) Partition coefficient	: 7.64(logP)
p) Auto ignition temperature	: No data available
q) Decomposition temperature	: No data available
r) Viscosity	: No data available
s) Explosive properties	: No data available
t) Oxidising properties	: No data available

Signature	Prepared by	Checked by	Approved by
			
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr. G. S. Patil	Mr. Kamman, R. S.	Mr. Venkatesh, S. Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA
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9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

No data available

10.3 Possibility of hazardous reaction

No data available

10.4 Condition to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - No data available

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: LD50: Oral, rat: LD50 = 4000 mg/kg;

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Genic cell mutagenicity

Signature	Prepared by	Checked by	Approved by
	<i>G.S. Patil</i>	<i>Kannan</i>	<i>Shrini</i>
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr. G.S. Patil	Mr. Kannan.R.S.	Mr. Venkatesh.S.Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA

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No data available

Carcinogenicity

IARC : No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Reproductive toxicity – rat – Oral

Paternal Effects : Prostate, seminal vesicle, Cowper's gland, accessory glands.

Developmental toxicity – rat – Oral

Effects on Embryo or Fetus: Other effects to embryo. Effects on Newborn: Growth statistics (e.g. reduced weight gain)

Specific target organ toxicity – single exposure

No data available

Specific target organ toxicity – repeated exposure

No data available

Potential health effects

Inhalation	: May be harmful if inhaled. May cause respiratory tract irritation
Ingestion	: May be harmful if swallowed
Skin	: May be harmful if absorbed through skin. May cause skin irritation
Eyes	: May cause eye irritation.

Sign and Symptoms of Exposure

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Additional information

RTRCS : EL8140000

12. ECOLOGICAL INFORMATION

Signature	Prepared by	Checked by	Approved by
	<i>G.S. Patil</i>	<i>Kannan</i>	<i>Shankar</i>
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr.G.S.Patil	Mr. Kannan.R.S.	Mr. Venkatesh.S.Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA

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12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with combustible solvent and burn in a chemical incinerator equipped with an after burner and scrubber.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1 UN-NUMBER

ADR/RID : -

IMDG : -

IATA : -

14.2 UN proper shipping name

ADR/RID : Not dangerous goods

Signature	Prepared by	Checked by	Approved by
	<i>G.S. Patil</i>	<i>R. Kannan</i>	<i>Shubh</i>
Date	02/02/2019	02/02/2019	02/02/2019
Name	Dr. G.S. Patil	Mr. Kannan, R.S.	Mr. Venkatesh, S. Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA

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SIGNATURE <i>Shubh</i>	DATE 11 JAN 2021

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IMDG : Not dangerous goods

IATA : Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID : -

IMDG : -

IATA : -

14.4 Packaging group

ADR/RID : -

IMDG : -

IATA : -

14.5 Environmental hazards

ADR/RID : -

IMDG: Marine pollutant: no IATA: -

14.6 Special precautions for users

No data available

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006

15.1 Safety health and environmental regulations/legislation specific for the substance or mixture

No data available

15.2 Chemical Safety Assessment

No data available

Signature	Prepared by <i>G.S. Patil</i>	Checked by <i>K.R.S. Kamran</i>	Approved by <i>V.S. Rao</i>
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr.G.S.Patil	Mr. Kamran.R.S.	Mr.Venkatesh.S.Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA

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12001 HCL CHEMICALS LIMITED, 12001 HCL CHEMICALS LIMITED, 12001 HCL CHEMICALS LIMITED

11 JAN 2021

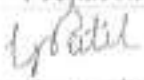
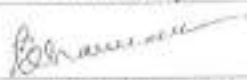
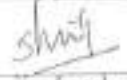
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16. OTHER INFORMATION

Reference: In house sources and sigmakdrich.com

Disclaimer:

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Signature	Prepared by	Checked by	Approved by
			
Date	01/02/2019	02/02/2019	02/02/2019
Name	Dr.G.S.Patil	Mr. Kaman.R.S.	Mr. Venkatesh.S.Rao
Designation	Scientist-R&D	HOD-Safety	

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 02 FEB 2019

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 11 JAN 2021

 HARMA LIMITED, UNIT II Bangalore	SAFETY DATA SHEET	MS / FP / 003
Supersedes document (if) Next Review date 02.02.2022		Revision No. 05 Effective date: 03.02.2019 Page No. 11 of 11

SECTION 17: DISTRIBUTION

SL.NO.	COPY NAME	DEPARTMENT
1	Master Copy	QA
2	Controlled Copy	QA
3	Controlled Copy	SHE
4	Controlled Copy	QC
5	Controlled Copy	MP
6	Controlled Copy	WH
7	Controlled Copy	R & D
8	Controlled Copy	PGWH

SECTION 18: REVISION HISTORY

Rev. No.	Reason for review	Effective Date
00	Fresh Issue	01.06.2012
01	MSDS updated as per CLP regulation	20.07.2012
02	Periodic Review	20.07.2015
03	Typographical Error	13.08.2015
04	Section 2.1 of version 03 removed and included safety phrases. Added Acute Toxicity in section 11.1.	04.02.2016
05	Periodic Review	03.02.2019

Signature	Prepared by	Checked by	Approved by
	<i>G.S. Patil</i>	<i>Kannan R.S.</i>	<i>Mr. Venkatesh S. Rao</i>
Date	01/02/2019	04/02/2019	02/02/2019
Name	Dr.G.S.Patil	Mr. Kannan.R.S.	Mr.Venkatesh.S.Rao
Designation	Scientist-R&D	HOD-Safety	HOD-QA



ANNEXURE-I

LIST OF MACHINERY

Section wise List of Production machinery	Document #:	CRY/PD/QF/ 008
	Version No:	01
	Issue date :	01-11-2023
	Next revision date	01-11-2025

1. TABLET SECTION

S.#	MACHINERY	EQ. ID	Supplier	Capacity	Qty
1	Double cone Mixer	PD-EQ-016	S.A engineering works Lahore	100 kg	01
2	Horizontal Blade Mixer	PD-EQ-002	S.A engineering works Lahore	150 kg	01
3	Rotary Granulator	PD-EQ-003	S.A engineering works Lahore	N/A	01
4	Oscillating Granulator	PD-EQ-004	S.A engineering works Lahore	N/A	01
5	Tray Dryer (40 trays)	PD-EQ-005	Haji Mushtaq and sons Lahore	100 kg	01
6	Rotary compression machine ZP- 31	PD-EQ-006	Shangai tianhe Pharmaceuticals machinery Ltd. China	74400 Tabs / hour	01
7	Rotary Tablet Compression machine ZP- 17	PD-EQ-009	Shangai tianhe Pharmaceuticals machinery Ltd. China	36720 Tabs/ hour	01
8	Air compressor	PD-EQ-007	China	500 bar 3 piston	01
9	Tablet Coating Pan	PD-EQ-010	Hamza engineers Rawat	10 kg	02
10		PD-EQ-011		35 kg	
11	Hot Air Blower	PD-EQ-012	S.A engineering works Lahore	N/A	01
12	Solution Preparation Vessel	PD-EQ-013	S.A engineering works LHR	50 liter	01
13	Silverson Mixer	PD-EQ-014	S.A engineering works	2850rpm	04

Prepared by: Production pharmacist	Reviewed by: Senior Production pharmacist	Verified by: Production Manager

Section wise List of Production machinery	Document #:	CRY/PD/QF/ 008
	Version No:	01
	Issue date :	01-11-2023
	Next revision date	01-11-2025

			Lahore		
14	Blister Packaging Machine DPB 250 ALU-ALU, ALU- PVC	PD-EQ-023	Zhejiang Hualian Pharmaceuticals Company China.	900 Strokes/ hour	01

2. SACHET SECTION

1	Double cone Mixer	PD-EQ-048	S.A engineering works Lahore	100 kg	01
2	Sachet Filling Machine	PD-EQ-047	Naveed engineering works Lahore	2700 Sachet/ hour	01

3. LIQUID SYRUP/ SUSPENSION SECTION

1	Liquid Syrup/ Suspension Mixing Tank	PD-EQ-061	Hajji Mushtaq and sons Lahore	1000 Liters	01
2	Liquid Syrup/ Suspension Filling Machine	PD-EQ-062	Hajji Mushtaq and sons Lahore	2000 Btls/hr	01
3	Liquid Syrup Filling Tank	PD-EQ-075	Haji Mushtaq and sons LHR.	200 Liter	01
4	Bottle Labeling Machine	PD-EQ-071	Haji Mushtaq and sons LHR	2000 Btl/hr	01
5	Transfer Pump	PD-EQ-073	Haji Mushtaq and sons Lahore	N/A	01
6	Filtration Assembly	PD-EQ-074	Haji Mushtaq and sons LHR	N/A	01
7	Bottle Blowing Machine	PD-EQ-063	Hajji Mushtaq and sons LHR.	N/A	01
8	S.S stocker	PD-EQ-085	Malhi brothers Eng Lahore	200 liter	01
9	Milling Machine	PD-EQ-065	Hajji Mushtaq and sons LHR	N/A	01
10	Silverson Mixer	PD-EQ-082	Malhi brothers Eng Lahore	2850 rpm	01

Prepared by: Production pharmacist	Reviewed by: Senior Production pharmacist	Verified by: Production Manager

Section wise List of Production machinery	Document #:	CRY/PD/QF/ 008
	Version No:	01
	Issue date :	01-11-2023
	Next revision date	01-11-2025

4. SOFT GELATIN CAPSULE					
1	Soft Gelatin Capsule Medicine manufacturing Tank	PD-EQ-064	Beijing Xinhangcheng Technology Development	100 liters	01
2	Drying Tumblers	PD-EQ-066	Beijing Xinhangcheng Technology Development	13 kg	04
3	Capsule Drying Trays	PD-EQ-067	Beijing Xinhangcheng Technology Development	3000 Cap/ Tray	80
4	Soft Gelatin Encapsulation Machine	PD-EQ-068	Beijing Xinhangcheng Technology Development	15000 Caps/ hr	01
5	Gelatin melting Kettle	PD-EQ-072	Beijing Xinhangcheng Technology Development	100 liter	02
6		PD-EQ-079			
7	Dehumidifier	PD-EQ-077	Sabro (local)	70 L/day	02
8	Vacuum Pump	PD-EQ-076	Beijing Xinhangcheng Technology Development	N/A	02
9		PD-EQ-078			
5. HARD GELATIN CAPSULE SECTION					
1	Double cone Mixer	PD-EQ-001	S.A engineering works Lahore	150 kg	01
2	Vacuum Cleaner	PD-EQ-015	Ruian Tianhong Pharma Machinery China	N/A	01
3	Automatic capsule filling machine	PD-EQ-018	Ruian Tianhong Pharma Machinery China	720 Cap/ minute	01
4	Capsule Polisher	PD-EQ-019	Ruian Tianhong Pharma Machinery China	N/A	01
5	Sampling rod	PD-EQ-017	Hamza engineers Rawat	N/A	01

Prepared by: Production pharmacist	Reviewed by: Senior Production pharmacist	Verified by: Production Manager

Section wise List of Production machinery	Document #:	CRY/PD/QF/ 008
	Version No:	01
	Issue date :	01-11-2023
	Next revision date	01-11-2025

6. TOPICAL GENERAL SECTION

1	Steam Jacketed Kettle	PD-EQ-020	Hajji Mushtaq and sons Lahore	300 Liter	02
2		PD-EQ-025	S.A engineering works Lahore	100 Liter	
3	Silverson Mixer	PD-EQ-029	S.A engineering works Lahore	2850 RPM	01
4	Cream Emulsifying Mixer	PD-EQ-032	Naveed Engineering Work Lahore	300 kg	01
5	Automatic Tube Filling Machine GLF-400	PD-EQ-027	Zhejiang Hualian Pharmaceuticals Company China.	3600 tubes/hr	01
6	Milling Machine	PD-EQ-034	S.A engineering works Lahore	N/A	01
7	Lotion Emulsifying Mixer	PD-EQ-069	Hajji Mushtaq and sons LHR.	600 kg	01
8	Manual lotion filling machine	PD-EQ-030	S.A engineering works Lahore	N/A	01
9	Vacuum Pump	PD-EQ-049	S.A engineering works Lahore	N/A	01
10	Bottle Blowing Machine	PD-EQ- 031	S.A engineering works Lahore	N/A	01
11	S.S stocker	PD-EQ-041	S.A engineering works Lahore	200 liter	05
12		PD-EQ-046	S.A engineering works Lahore	200 liter	
13		PD-EQ-043	S.A engineering works Lahore	100 liter	
14		PD-EQ-083	S.A engineering works	20 liter	

Prepared by: Production pharmacist	Reviewed by: Senior Production pharmacist	Verified by: Production Manager

Section wise List of Production machinery	Document #:	CRY/PD/QF/ 008
	Version No:	01
	Issue date :	01-11-2023
	Next revision date	01-11-2025

			Lahore		
15		PD-EQ-080	Hajji Mushtaq and sons LHR.	400 liter	
7. TOPICAL STEROID SECTION					
1	Cream Emulsifying Mixer	PD-EQ-033	Friends engineering works	500 kg	01
2	Semi automatic Tube Filling Machine	PD-EQ-045	Nantong Tongzhou machinery manufacturer china	1800 Tubes/ hour	01
3	Semiautomatic lotion filling machine	PD-EQ-021	Local supplier	1000 Btls/Hour	01
4	Steam Jacketed Kettle	PD-EQ-020	Hajji Mushtaq and sons Lahore	300 Liter	01
5		PD-EQ-026	S.A engineering works Lahore	100 Liter	01
6	Silverson Mixer	PD-EQ-030	S.A engineering works Lahore	2850 RPM	01
7	Milling Machine	PD-EQ-044	S.A engineering works Lahore	N/A	01
8	Bottle Blowing Machine	PD-EQ-040	S.A engineering works Lahore	N/A	01
9	S.S stocker	PD-EQ-039	S.A engineering works Lahore	200 liter	03
10		PD-EQ-042	S.A engineering works Lahore	100 liter	
11		PD-EQ-055	Malhi brothers Eng Lahore	200 liter	
8. RESEARCH & DEVELOPMENT					
1	Oscillating Granulator	PD-EQ-052	S.A engineering works Lahore	N/A	01

Prepared by: Production pharmacist	Reviewed by: Senior Production pharmacist	Verified by: Production Manager

Section wise List of Production machinery	Document #:	CRY/PD/QF/ 008
	Version No:	01
	Issue date :	01-11-2023
	Next revision date	01-11-2025

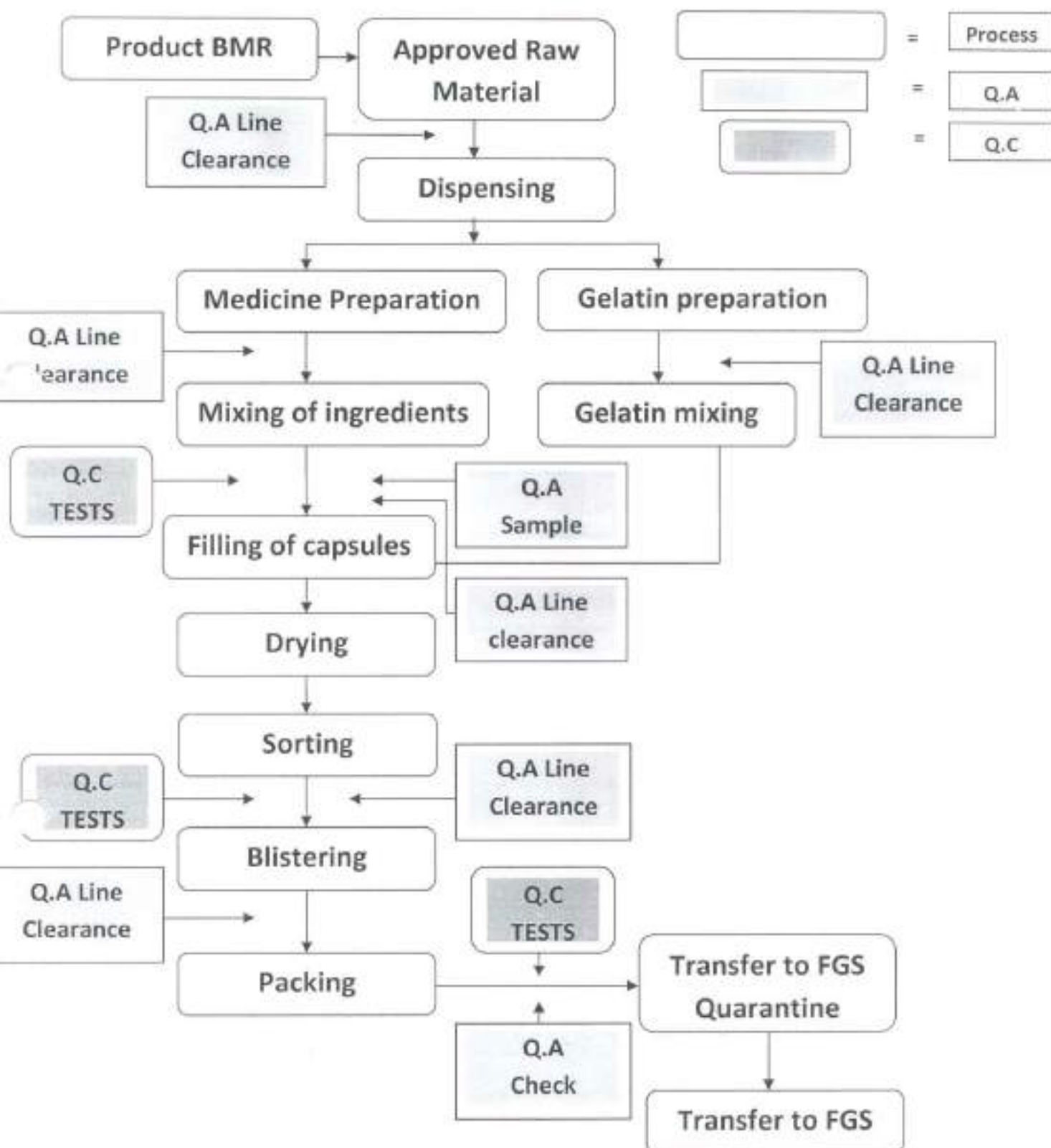
2	Tablet Coating Pan	PD-EQ-053	S.A engineering works Lahore	2 kg	01
3	Horizontal Blade Mixer	PD-EQ-054	S.A engineering works Lahore	2 kg	01
4	Hot Air Blower	PD-EQ-056	S.A engineering works Lahore	N/A	01
5	Double cone Mixer	PD-EQ-057	S.A engineering works Lahore	2 kg	01
9. PACKING HALL					
1	Packing conveyor Belt	PD-EQ-008	S.A engineering works Lahore	16 feet	02
2		PD-EQ-036		16 feet	
3	Ink jet Printer	PD-EQ-038	Markem-Image corporation Suzhou China	3500/hr	02
4	Ink jet Printer	PD-EQ-035		3500/hr	
5	Smart lase C150 printer	PD-EQ-022	Markem-Image corporation Suzhou China		01
6	Automatic folding machine ZE series	PD-EQ-058	China	80 m/ minute	01
7	Round bottle labeling machine	PD-EQ-059	China	N/A	01

Prepared by: Production pharmacist	Reviewed by: Senior Production pharmacist	Verified by: Production Manager

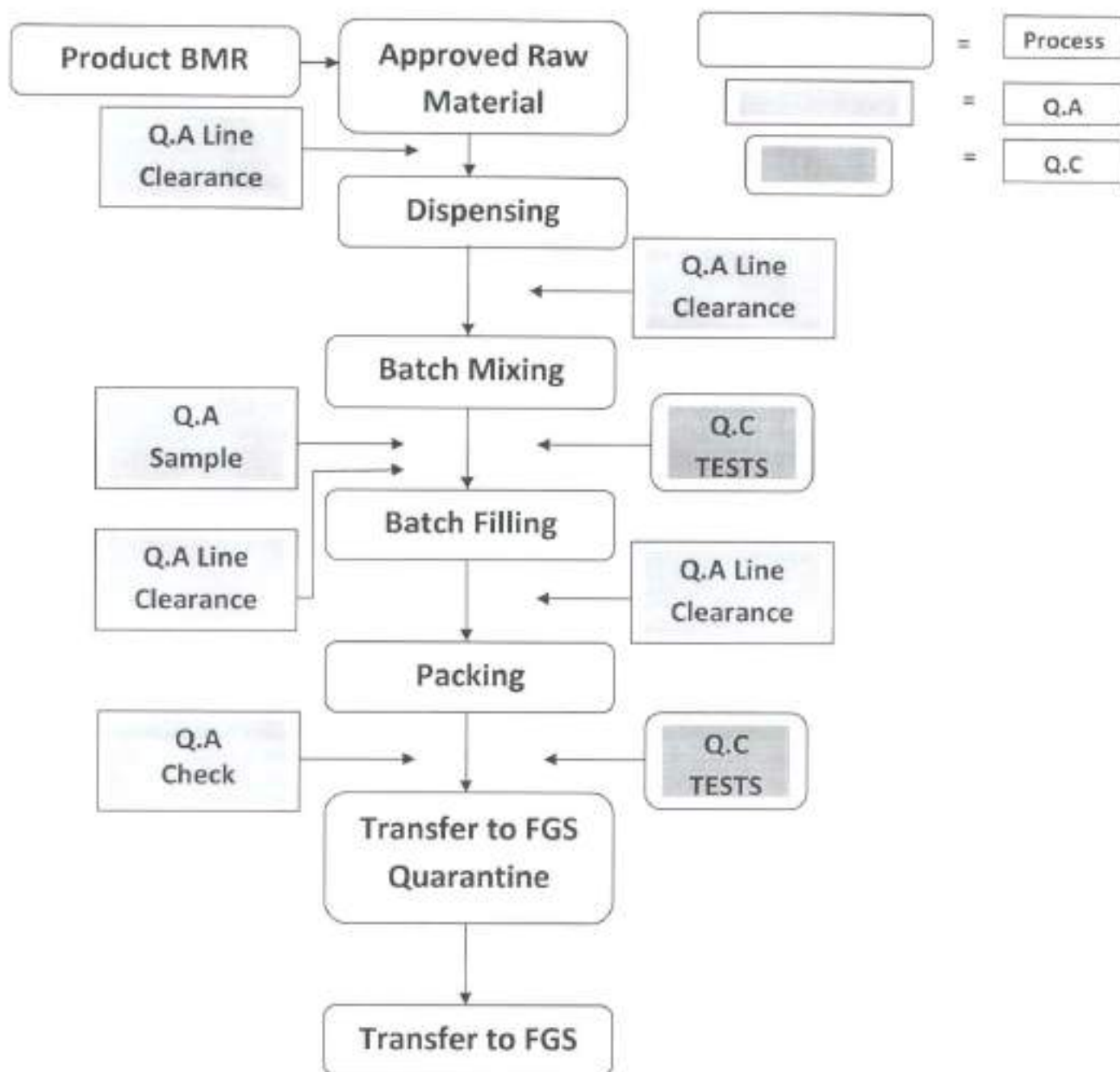
ANNEXURE-J

***FLOW CHART OF CRYSTOLITE
PHARMACEUTICALS***

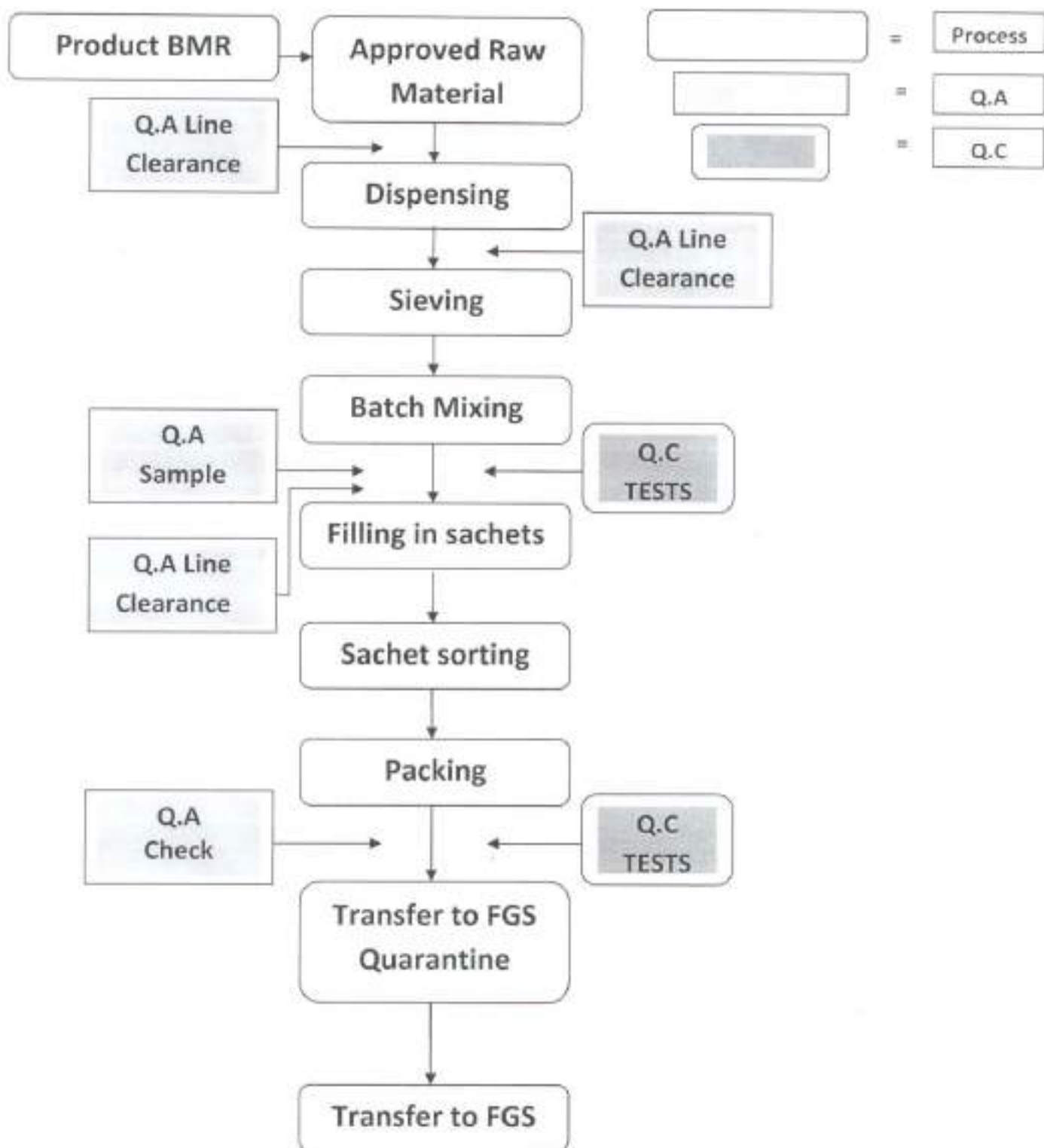
PROCESS FLOW CHART OF SOFT GELATIN CAPSULE SECTION



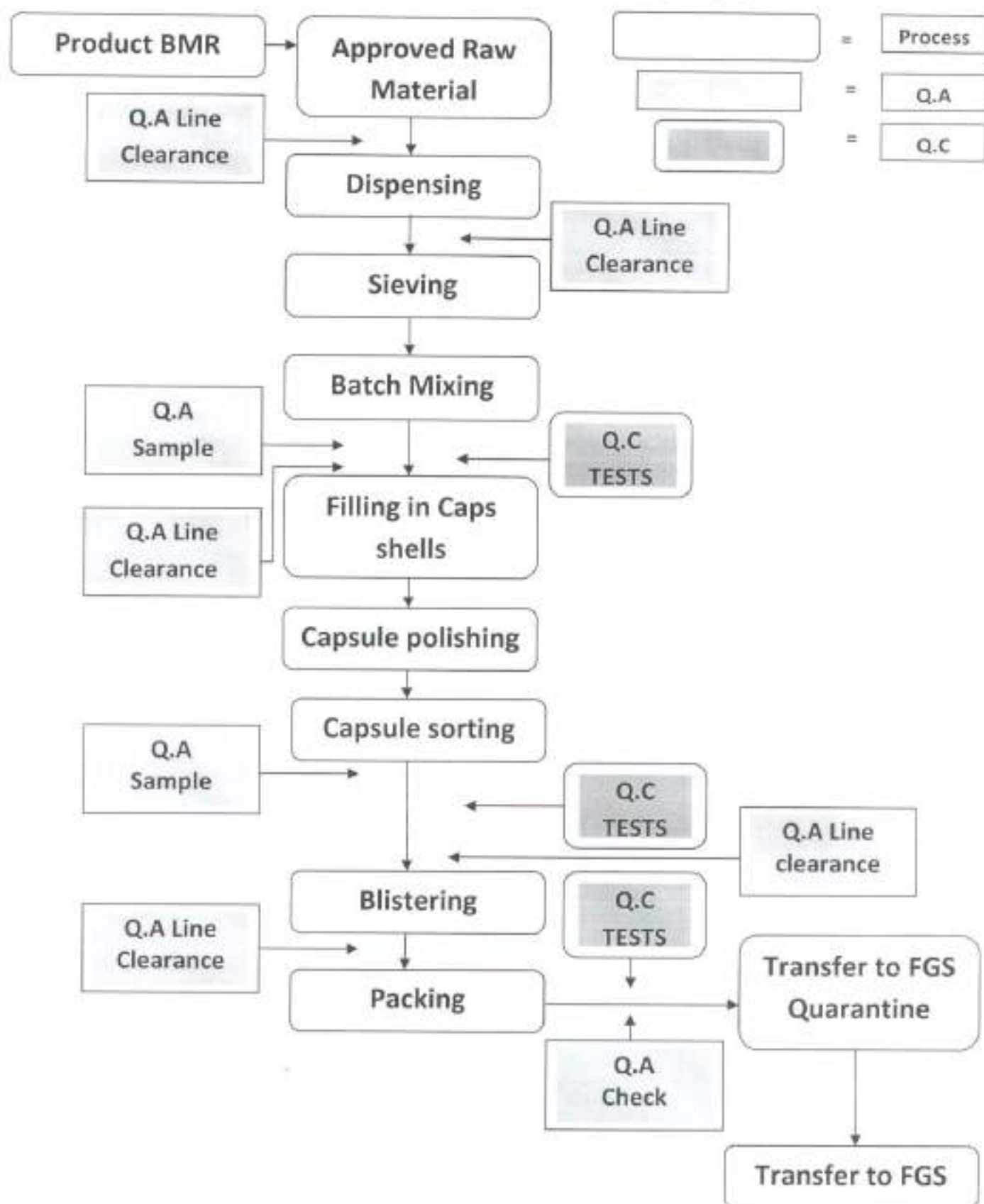
PROCESS FLOW CHART OF TOPICAL SECTION



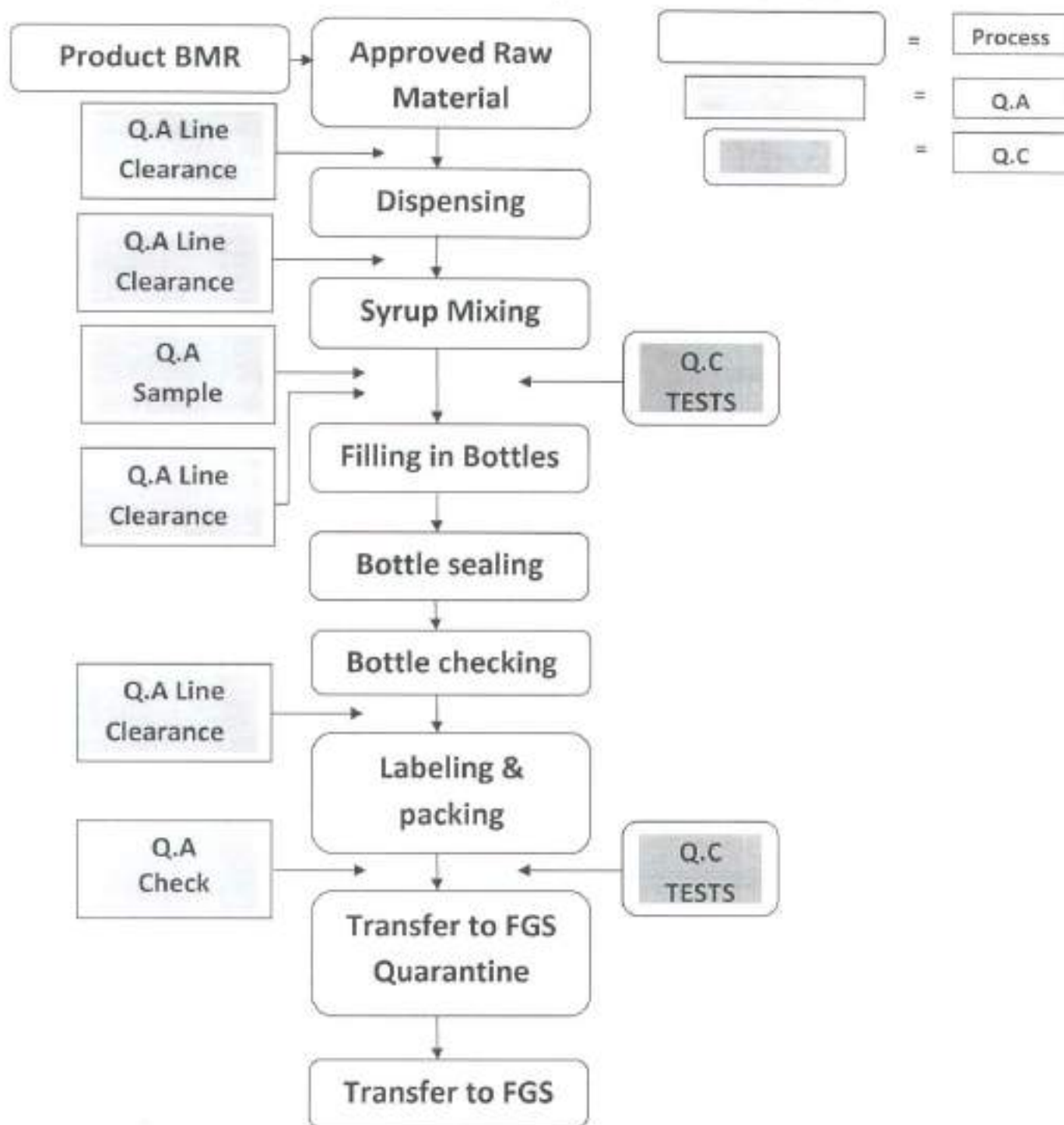
PROCESS FLOW CHART OF SACHET SECTION



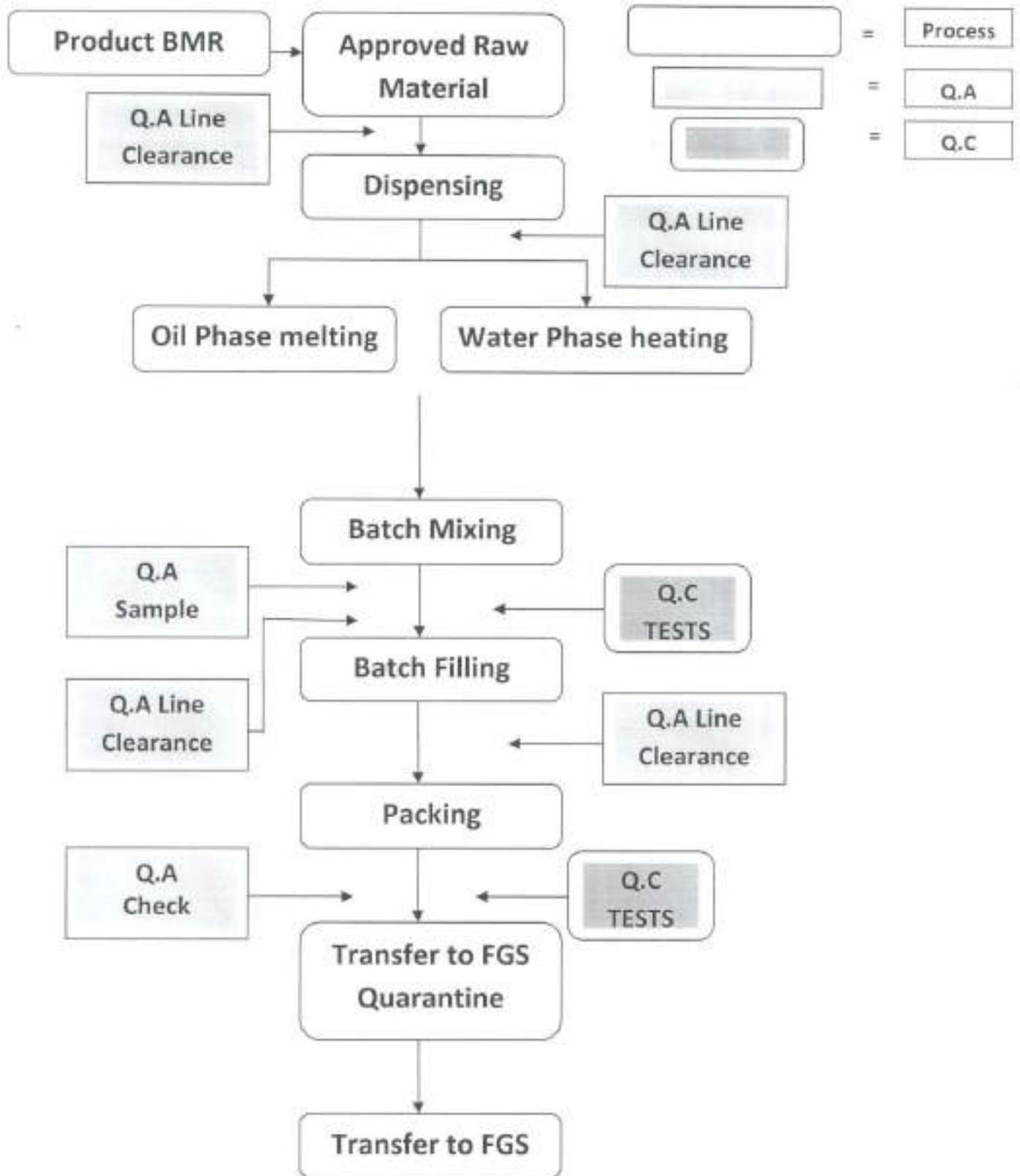
PROCESS FLOW CHART OF CAPSULE SECTION



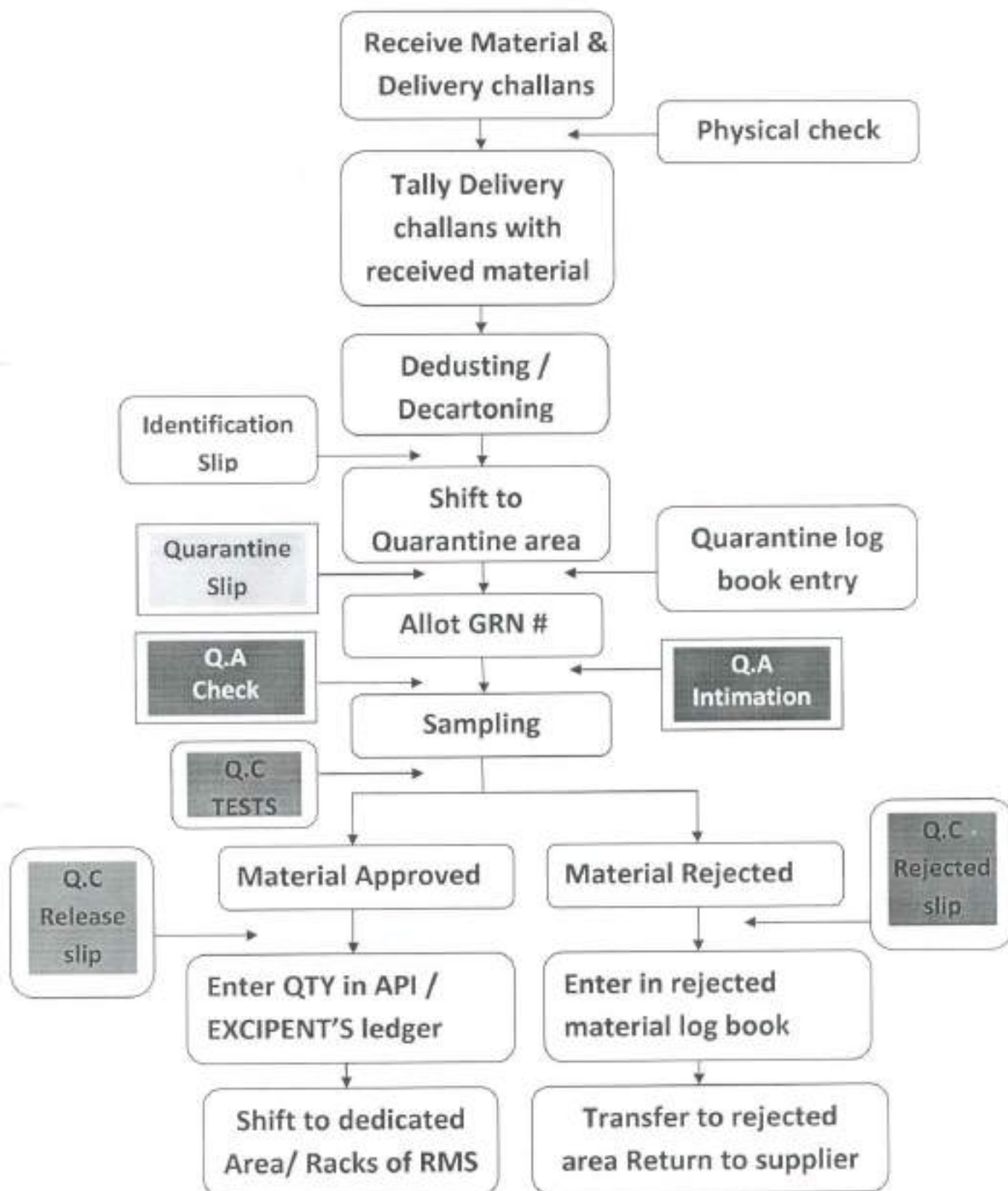
PROCESS FLOW CHART OF LIQUID SYRUP SECTION



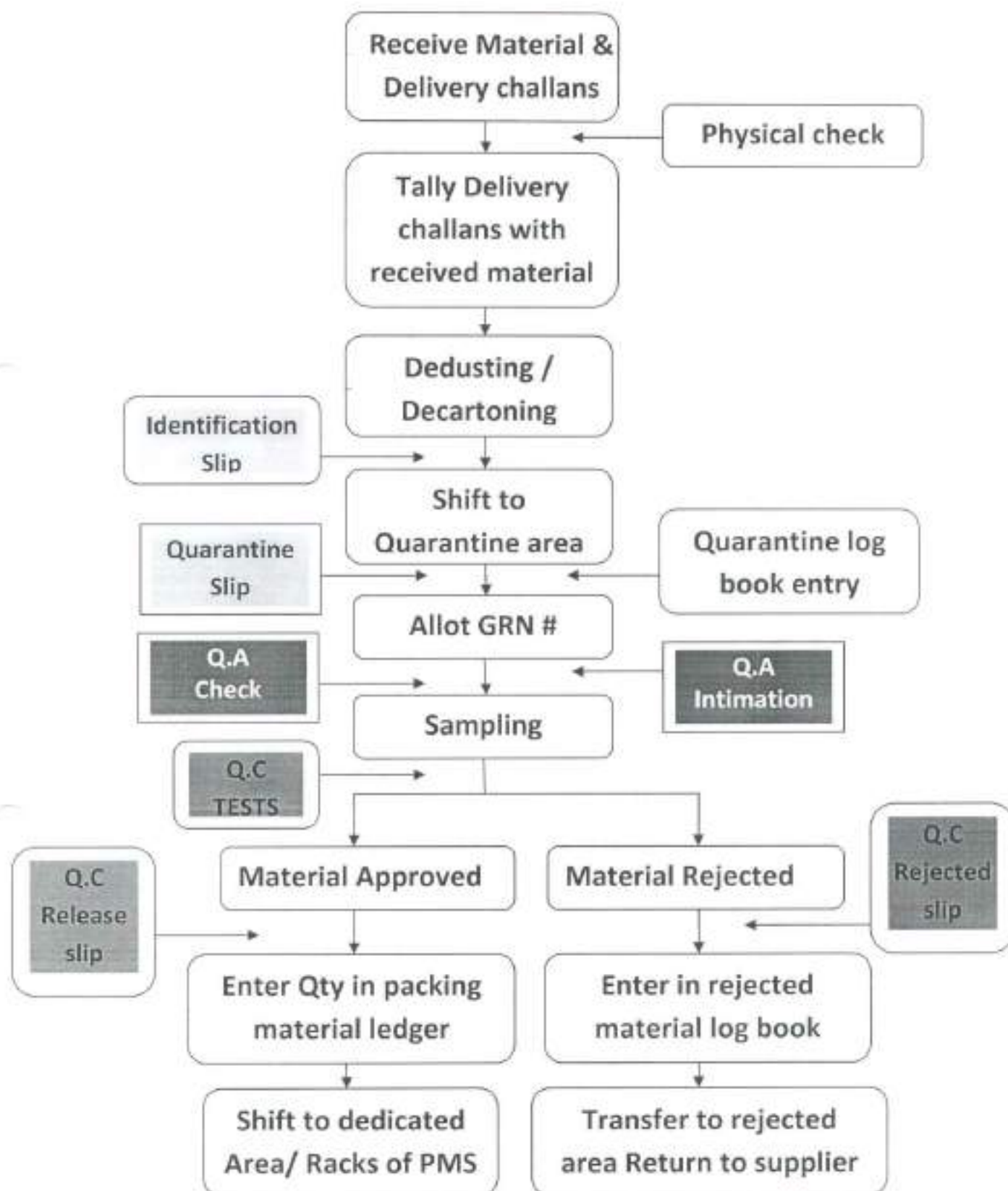
PROCESS FLOW CHART OF TOPICAL SECTION



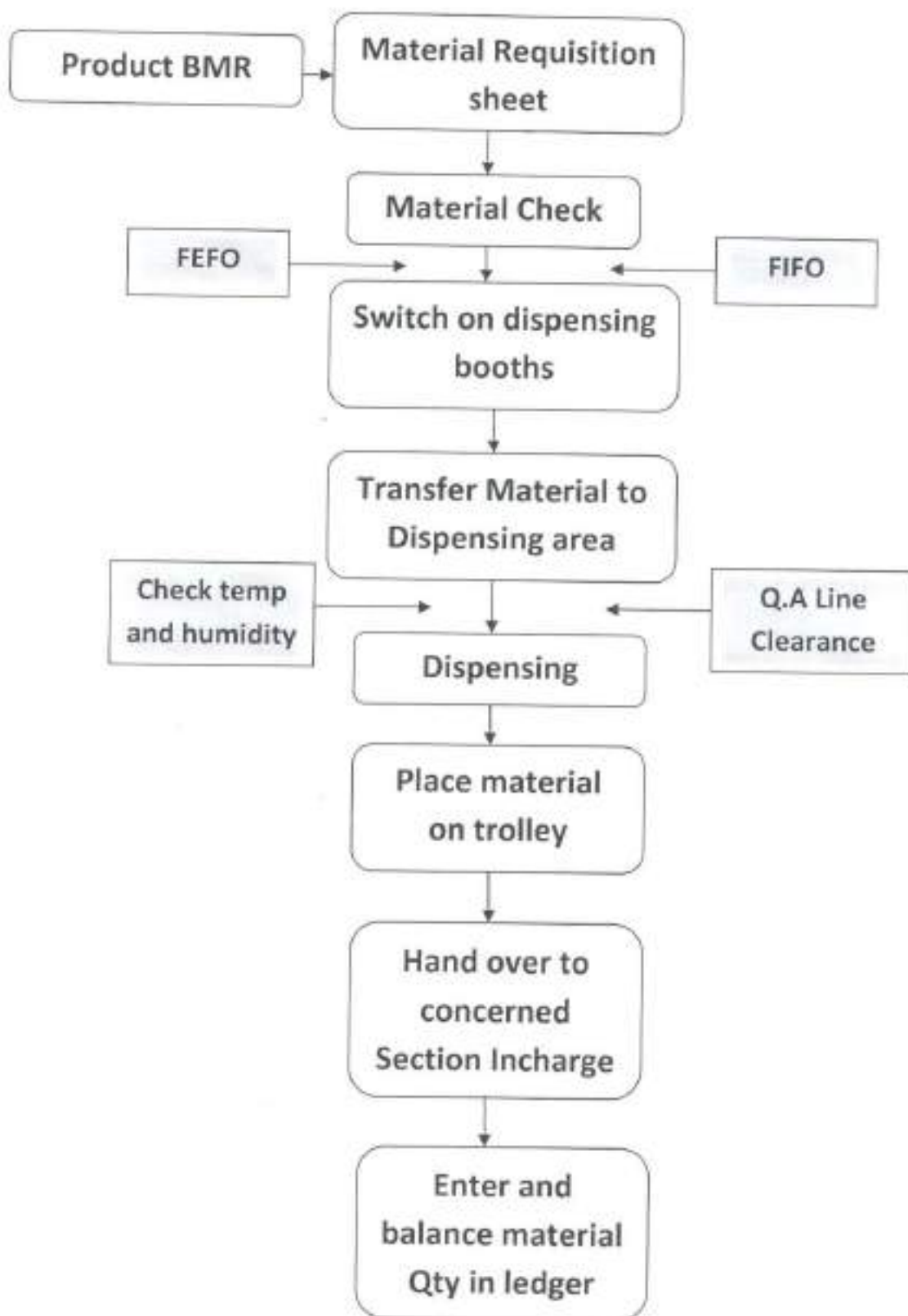
PROCESS FLOW CHART OF RAW MATERIAL



PROCESS FLOW CHART OF PACKING MATERIAL RECEIVING



FLOW CHART OF DISPENSING



ANNEXURE-K

SOPS FOR WASTE MANAGEMENT

Crystolite Pharmaceuticals		Document No.	CRY/QA/SOP/020
 CRYSTOLITE PHARMACEUTICALS ISO 9001: 2015 Certified Co.	STANDARD OPERATING PROCEDURE	Effective Date:	17-08-2023
		Revision No.	02
		Next Revision Date:	Aug 2026
		Controlled Copy No.	01
TITLE: SOP FOR FACTORY WASTE MANAGEMENT			

1. PURPOSE:

The purpose of this SOP is to provide guidelines about waste Management.

2. SCOPE:

It is applicable to all the Departments of Crystolite Pharmaceuticals.

3. RESPONSIBILITY:

Quality Assurance Manager (QAM) is authorized to approve, revise, issue and implement this sop while Quality Assurance staff is responsible to follow this sop. QCM is responsible to review this SOP.

4. REVISION FREQUENCY:

This SOP will be reviewed at least once every three years and revised if required as per recommendations of Quality Assurance manager (QAM) or as per guidance from departmental heads or regulatory requirement or change in concerned specification, process or equipment.

5. PROCEDURE:

TYPES OF WASTES:

This system deals with three types of wastes namely:

- Solid waste
- Liquid waste
- Gaseous waste

Solid Waste:

The solid wastes may be of following types:

Powders:

- Dust generated during dispensing and production processes.
- Rejected, expired and spilled raw materials.
- Leftover sample (in powder form) for testing in laboratories.
- Expired or rejected chemicals from laboratories.

Prepared by: Sign:  Name: Ahmad Hayat Khan Designation: Quality Assurance Officer	Reviewed by: Sign:  Name: Amir Raza Designation: Q.C Manager	Approved by: Sign:  Name: Ayesha Mumtaz Designation: Quality Assurance Manager

**STANDARD OPERATING
PROCEDURE**

Document No.	CRY/QA/SOP/020
Effective Date:	17-08-2023
Revision No.	02
Next Revision Date:	Aug 2026
Controlled Copy No.	01

TITLE: SOP FOR FACTORY WASTE MANAGEMENT

Actives: Penicillin waste:

- Waste from microbiological laboratory

Inert: Primary Packaging Materials

- Aluminum foil/PVC film nets and cuttings.
- Rejected or discontinued aluminum foil or PVC film.
- Damaged or broken glass bottles and plastic containers.

Secondary Packaging Materials:

- Leftover printed labels and cartons.
- Discontinued, soiled and rejected materials.

Others:

- Empty metallic or plastic drums/containers (raw materials).
- Used or rejected polythene bags.
- Wooden scrap.
- PVC pipes etc.
- Chemical bottles, glass or plastic from laboratories.
- Office waste containing papers boards etc.

LIQUID WASTE:

- **Smoke:**
From boiler.
- **Fine dust:**
From manufacturing operations.

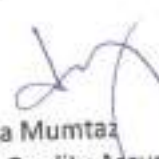
WASTE ACCUMULATION, CONTROL & DISPOSAL SYSTEM:

Precautions:

- While accumulating the waste take maximum care to avoid Penicillin and other highly combustible or explosive materials or products.
- Use gloves, safety glasses and disposable mask while accumulating the wastes.

Gaseous Wastes:

- Contains smoke from boiler and fine dust from manufacturing operations.

Prepared by:	Reviewed by:	Approved by:
Sign: 	Sign: 	Sign: 
Name: Ahmad Hayat Khan Designation: Quality Assurance Officer	Name: Amir Raza Designation: Q.C Manager	Name: Ayesha Mumtaz Designation: Quality Assurance Manager



STANDARD OPERATING PROCEDURE

Document No.	CRY/QA/SOP/020
Effective Date:	17-08-2023
Revision No.	02
Next Revision Date:	Aug 2026
Controlled Copy No.	01

TITLE: SOP FOR FACTORY WASTE MANAGEMENT

- These emissions are minor and controlled as under:
- Boiler is forced draft, oil fired type having complete combustion not endangering the environment.
- Boiler is properly maintained by qualified and experienced Boiler Engineer and annually inspected and certified by External Authorized Agency.
- All dust generating operations/equipment have built in DCUs.
 - Quality assurance and the production will arrange destruction following the procedure given below:

Redressing and Destruction of Solis Stock

Dry Products:

- Tablets or capsules will be removed from the blisters/containers and collected in clean plastic buckets.
- The content of bucket (if less than 5kg) will then be soaked in water and allowed to disintegrate completely.
- The disintegrated tablets will be drained in small portions with continuous flow of large amount of water.
- If sufficient quantity is accumulated (more than 5kg) then it will be disposed off through incineration.
- Empty cartons/containers will be disposed off after making them no usable.
- Empty blisters will be disposed off after crushing on shredder.

Liquid Products:

- Bottles will be emptied in a plastic bucket and soaked into water to detach the labels.
- Empty bottles, caps, cartons/direction slips will be stored separately.
- The contents of the bucket will be drained with continuous flow of large amount of water.
- Empty bottles and caps will be disposed off after crushing.
- Labels, direction slips and empty cartons will be disposed off after making them non usable.

Creams / Gels:

- Tubes will be emptied into a plastic bucket containing hot water which will be drained after vigorous stirring and with continuous flow of water.

Prepared by:	Reviewed by:	Approved by:
Sign:	Sign:	Sign:
Name: Ahmad Hayat Khan Designation: Quality Assurance Officer	Name: Amir Raza Designation: Q.C Manager	Name: Ayesha Mumtaz Designation: Quality Assurance Manager

**STANDARD OPERATING
PROCEDURE**

Document No.	CRY/QA/SOP/020
Effective Date:	17-08-2023
Revision No.	02
Next Revision Date:	Aug 2026
Controlled Copy No.	01

TITLE: SOP FOR FACTORY WASTE MANAGEMENT

- Plastic caps and tubes will be disposed off after making them non usable.
- Empty cartons and direction slips will be disposed off after making them non usable.

Redressible Stocks:

- Production officer will arrange packaging materials with appropriate coding.
- Get line clearance before starting redressing operation.
- Supervise redressing operation.
- Concerned production officer will prepare separate batch card for each batch mentioning quantities of packaging materials required.
- This document will become the part of batch documents.
- After complete releasing production will transfer the stock to warehouse with a copy to QA, for issuance of Redressing/Destruction certificate accordingly to the concerned department.

8. DISTRIBUTION LIST:

1. Quality Assurance Manager
2. Quality Control Department
3. Tablet/capsule
4. Liquid
5. Topical Manufacturing & Packing
6. RMS
7. Audit

AMENDMENT HISTORY

Rev. #	Date	Initiated By	Page #	Nature of Amendment	Approved By
00	24-1-22	QAI	--	Reviewed	QAM
01	17-08-23	Q.A Manager	All pages	New format of SOP applied.	QAM

Prepared by: Sign:  Name: Ahmad Hayat Khan Designation: Quality Assurance Officer	Reviewed by: Sign:  Name: Amir Raza Designation: Q.C Manager	Approved by: Sign:  Name: Ayesha Mumtaz Designation: Quality Assurance Manager

ANNEXURE-L

*SOPS FOR EMERGENCY PREPAREDNESS
AND RESPONSE*

**STANDARD OPERATING
PROCEDURE**

Document No.	CRY/CW/SOP/007
Effective Date:	10-06-2023
Revision No.	02
Next Revision Date:	MAY 2026
Controlled Copy No.	01

ISO 9001: 2015 Certified Co.

TITLE: STANDARD OPERATING PROCEDURE FOR EMERGENCY PREPAREDNESS AND RESPONSE (EP&R)**1. PURPOSE:**

- This procedure is written and implemented to save the humans, material, machines, building and other properties during emergency.
- By implementing this procedure people are able to prepare themselves and respond adequately during emergency for handling the emergency situation.

2. SCOPE:

This procedure applies to all over the factory premises in any kind of activities of the factory any where anytime (24 hours).

3. RESPONSIBILITY:

Quality Assurance (QAM) is authorized to approve this procedure and QCM is responsible for the revision of this procedure while Factory staff including Managers, incharges Officers and workers is responsible to execute, implement and follow this procedure.

4. REVISION FREQUENCY:

This SOP will be reviewed at least once every three years and revised if required as per recommendations of Quality Assurance manager (QAM) or as per guidance from departmental heads or regulatory requirement or change in concerned specification, process or equipment.

5. PROCEDURE:**First Aid/medical facility:**

In order to deal emergency and provide first aid to factory staff a well equipped first aid box is placed near quality control for easy access. Keeping in view the severity of the incident patient is shifted to near by hospital for further treatment.

Prepared by:

Sign:

Name: Ahmad Hayat Khan

Designation: Quality Assurance Officer

Reviewed by:

Sign:

Name: Amir Raza

Designation: Q.C Manager

Approved by:

Sign:

Name: Ayesha Mumtaz

Designation: Quality Assurance Manager

Crystolite Pharmaceuticals



STANDARD OPERATING PROCEDURE

Document No.	CRY/CW/SOP/007
Effective Date:	10-06-2023
Revision No.	02
Next Revision Date:	MAY 2026
Controlled Copy No.	01

TITLE: STANDARD OPERATING PROCEDURE FOR EMERGENCY PREPAREDNESS AND RESPONSE (EP&R)

Medical checkups and necessary blood tests of employees are carried out by social security hospital or any other hospital once in a year.

Accident with machines:

Emergencies arising out of working methods, machines and equipment are handled in the factory. Selected personnel are trained to impart first aid to the concerned person in case of emergency. Having administered first aid wherever needed according to the expertise available, section incharge intimates the Admin. manager for transfer of the affected person to the nearest hospital for medical aid.

Note:

This procedure is reviewed after the occurrence of any emergency and revised if required.

6. DISTRIBUTION LIST:

1. Quality Assurance Manager.
2. Manager Production.
3. Quality Control Manager.
4. Incharge Raw Material Store.
5. Incharge Finished Goods Store.
6. For Audit.

AMENDMENT HISTORY

Rev. #	Date	Initiated By	Page #	Nature of Amendment	Approved By
00	20-1-22	QAI	--	Reviewed	QAM
01	10-06-23	Q.A Manager	All pages	New format of sop applied.	QAM

Prepared by:	Reviewed by:	Approved by:
Sign:	Sign:	Sign:
Name: Ahmad Hayat Khan Designation: Quality Assurance Officer	Name: Amir Raza Designation: Q.C Manager	Name: Ayesha Mumtaz Designation: Quality Assurance Manager

ANNEXURE-M

*SOPS AND LIST OF FIRE
EXTINGUISHERS*

**STANDARD OPERATING
PROCEDURE**

Document No.	CRY/CW/SOP/020
Effective Date:	10-06-2023
Revision No.	02
Next Revision Date:	MAY 2026
Controlled Copy No.	01

TITLE: STANDARD OPERATING PROCEDURE FOR FIRE EXTINGUISHERS**1. PURPOSE:**

- This procedure is written and implemented to save the humans, material, machines, building and other properties during emergency.
- The purpose of this Standard operating procedure is to provide an operating procedure for the fire extinguishers.

2. SCOPE:

The procedure is relevant for Fire Extinguishers in industries.

3. RESPONSIBILITY:

Quality Assurance (QAM) is authorized to approve this procedure and QCM is responsible for the revision of this procedure while Factory staff including Managers, incharges Officers and workers is responsible to execute, implement and follow this procedure.

4. REVISION FREQUENCY:

This SOP will be reviewed at least once every three years and revised if required as per recommendations of Quality Assurance manager (QAM) or as per guidance from departmental heads or regulatory requirement or change in concerned specification, process or equipment.

5. PROCEDURE:

Fire is classified into four types based on its usage:

Class A Fire: For All solid fires

Class B Fire: For All liquid fires

Class C Fire: For All gas fires

Class D Fire: For All metal fires

Fires should be extinguished by using the different extinguishers as given below:

Class A fire – Water and CO2 types Mechanical foam type extinguishers.

Class B fire – Foam, Dry chemical powder (DCP), and carbon dioxide extinguishers.

Class C fire – Dry chemical powder (DCP) and carbon dioxide extinguishers.

Prepared by:	Reviewed by:	Approved by:
Sign:	Sign:	Sign:
Name: Ahmad Hayat Khan Designation: Quality Assurance Officer	Name: Amir Raza Designation: Q.C Manager	Name: Ayesha Mumtaz Designation: Quality Assurance Manager



STANDARD OPERATING PROCEDURE

Document No.	CRY/CW/SOP/020
Effective Date:	10-06-2023
Revision No.	02
Next Revision Date:	MAY 2026
Controlled Copy No.	01

TITLE: STANDARD OPERATING PROCEDURE FOR FIRE EXTINGUISHERS

Class D fire – Extinguisher with special dry powder metal fires.

Dry Chemical Powder type (DCP):

- Squeeze grip nozzle type dry chemical powder fire extinguisher' (9, 50, 150) liter capacity.
- Take the extinguisher and position yourself on the upwind side of the fire, about 5 to 8 feet away. Remove the extinguisher's safety ring.
- With one hand, hold the squeeze grip nozzle and point it at the fire, and With the other hand, tap the knob.
- Apply pressure to the squeeze grip nozzle to push the powder around the fire's center.
- As the pressure decreases, move the nozzle quickly in a side-to-side motion.
- Use a new fire extinguisher if the current one runs out or fight the fire until the flames go out.

Carbon dioxide type:

- Take the extinguisher and move away from the flames by 5 to 8 feet.
- Be on the fire's upwind side.
- Remove the safety ring/pin, if provided.
- Hold the horn in one hand and direct it towards the fire with the other hand, turn the valve in an anti-clockwise direction in order to get the required pressure and jet length.
- Carry the extinguisher with the help of a handle, direct the jet at the base of the fire, and operate in a sweeping motion. Proceed towards the fire and be as close as possible to the fire,
- Fight the fire till the flame disappears or the extinguisher becomes empty.

Note: Most suitable for indoor fires and on fires in electrical equipment. If the horn is of metal type, then do not use the same extinguisher on electrically live equipment or cable or electrical fire. Ventilate the area after use. In case of a major fire, the hydrant system can be operated by the safety squad.

Prepared by:	Reviewed by:	Approved by:
Sign:	Sign:	Sign:
Name: Ahmad Hayat Khan Designation: Quality Assurance Officer	Name: Amir Raza Designation: Q.C Manager	Name: Ayesha Mumtaz Designation: Quality Assurance Manager

Crystolite Pharmaceuticals



STANDARD OPERATING PROCEDURE

Document No.	CRY/CW/SOP/020
Effective Date:	10-06-2023
Revision No.	02
Next Revision Date:	MAY 2026
Controlled Copy No.	01

TITLE: STANDARD OPERATING PROCEDURE FOR FIRE EXTINGUISHERS

6. DISTRIBUTION LIST:

1. Quality Assurance Manager.
2. Manager Production.
3. Quality Control Manager.
4. Incharge Raw Material Store.
5. Incharge Finished Goods Store.
6. For Audit.

AMENDMENT HISTORY

Rev. #	Date	Initiated By	Page #	Nature of Amendment	Approved By
00	20-1-22	QAI	--	Reviewed	QAM
01	10-06-23	Q.A Manager	All pages	New format of sop applied.	QAM

Prepared by:

Sign:

Name: Ahmad Hayat Khan
Designation: Quality Assurance Officer

Reviewed by:

Sign:

Name: Amir Raza
Designation: Q.C Manager

Approved by:

Sign:

Name: Ayesha Mumtaz
Designation: Quality Assurance Manager

LIST OF FIRE EXTINGUISHERS

Sr.No	Fire Extinguisher ID	Type	Capacity(kg)	Location	Refill date	Due date
1.	EQ-F.EX.01	DCP	06kg	RMS (liquid)	24-10-23	23-10-24
2.	EQ-F.EX.02	CO2	03kg	Corridor (FGS)	24-10-23	23-10-24
3.	EQ-F.EX.03	DCP	04kg	Corridor (topical section)	24-10-23	23-10-24
4.	EQ-F.EX.04	DCP	06kg	Mess	24-10-23	23-10-24
5.	EQ-F.EX.05	CO2	05kg	Corridor (Packing hall 2)	24-10-23	23-10-24
6.	EQ-F.EX.06	CO2	05kg	Steroid section	24-10-23	23-10-24
7.	EQ-F.EX.07	CO2	05kg	Corridor (RMS)	24-10-23	23-10-24
8.	EQ-F.EX.08	DCP	05kg	Corridor (softgel section)	24-10-23	23-10-24
9.	EQ-F.EX.09	DCP	06kg	Guard room	24-10-23	23-10-24
10.	EQ-F.EX.10	DCP	04kg	Raw material store (liquid section)	24-10-23	23-10-24


QA Manager

ANNEXURE-N

RAWAT MAINTENANCE SLIP

RCCI INDUSTRIAL ESTATE RAWAT

Customer Copy

Monthly Maint Bill & One Time Charges
2746

Member Name Ali Raza S/o Sayed Mazhar ul Hassan
House /Bldg 326 Street/Block 34E
Type Industrial Unit
Billing Period January-2024
Plot Size Sq.Yd 21600
Issuing Date 05/01/2024 Due Date 15/01/2024

MONTHLY BILLING

Rs. 5,000

ARREARS:

One Time Dev. Charges	Rs. 650,000
Monthly Maint. Charges	Rs. 303,388
Total Arrears	Rs. 953,388
1% Surcharge, if any	Rs. 9,534
G.Total	Rs. 967,922

INSTRUCTIONS:

- 1) Bill will be deposited in Al-Baraka Bank Through Cash
Deposit Slip/Online/DD/P.O/Chq
- 2) 1% will be charged as 'LATE FEE' after due date.
- 3) It is mandatory to Send an email your deposit/Online Receipt
to renaissancedev@yahoo.com
- 4) What'sApp: 0310-8141417

Cash/D.D/P.O/C.C, Online

Date: _____

ANNEXURE-0

STAKEHOLDER' CONSULTATION FORMS

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name: M. Wabab
Residence: Rawalpindi
Gender: ☒ M ☐ F
Qualification: B.A

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☐	☒	☐	☐	☐
Will the project increase the importance of the area?	☒	☐	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☒	☐	☐	☐	☐


Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

M. Basir

Residence:

Kawalpindi

Gender:



Qualification:

B. Com

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

Khalid

Residence:

Islamabad

Gender:

☒ M

☐ F

Qualification:

FSC

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

Kusar B. B.
Rawalpindi

Residence:

Gender:

☐ M☒ F

Qualification:

Matric

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☐	☒	☐	☐	☐
Will the project increase the importance of the area?	☒	☐	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

Madia Bibi

Residence:

Islamabad

Gender:

☐ M

☒ F

Qualification:

F.A

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☒	☐	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

M. Muneeb

Residence:

Rawalpindi

Gender:

☒ M☐ F

Qualification:

Matric

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☐	☒	☐	☐	☐
Will the project increase the importance of the area?	☒	☐	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☐	☒
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

Khuram

Residence:

Rawalpindi

Gender:



Qualification:

F.A

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☒	☐	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name: Abdul Rehman
Residence: Rawalpindi
Gender: ☒ M ☐ F
Qualification: BSC

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

Nawazish Ali

Residence:

Rawalpindi

Gender:



Qualification:

M.A

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☒	☐	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name: Ghulam Rasool
Residence: Islamabad
Gender: ☒ M ☐ F
Qualification: M.com

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐


Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

M. Faiz

Residence:

Islamabad

Gender:



Qualification:

Matric

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☐	☒	☐	☐	☐
Will the project increase the importance of the area?	☒	☐	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐


Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name: M. Maali
Residence: Islamabad
Gender: ☒ M ☐ F
Qualification: B. Com

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☒	☐	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐


Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

Ustafa

Residence:

Rawat

Gender:

☒ M

☐ F

Qualification:

FA

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☒	☐	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name: Sajid
Residence: Kalu
Gender: ☒ M ☐ F
Qualification: Matric

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☒	☐	☐	☐	☐
Will the project increase the importance of the area?	☐	☒	☐	☐	☐
Will the project help to improve the living standards of the area?	☒	☐	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☐	☒
Level of satisfaction?	☒	☐	☐	☐	☐


Signature of Interviewer

Public Consultation/ Stakeholder Participation Regarding EIA

M/S Crystolite pharmaceuticals

Name:

U. Wajman

Residence:

Kali

Gender:



Qualification:

Natric

REMARKS

	Strongly agree	Agree	No comments	Disagree	Strongly disagree
Are you in favor of the proposed construction?	☐	☒	☐	☐	☐
Will the project increase the importance of the area?	☒	☐	☐	☐	☐
Will the project help to improve the living standards of the area?	☐	☒	☐	☐	☐
Will the project affect the environment of the area?	☐	☐	☐	☒	☐
Level of satisfaction?	☐	☒	☐	☐	☐



Signature of Interviewer

ANNEXURE-P

LIST OF ABBREVIATIONS

LIST OF ABBREVIATIONS

OSHA	Occupational Safety and Health Administration
EPA Punjab	Environmental Protection Agency, Punjab
EIA	Environmental Impact Assessment
IEE	Initial Environmental Examination
NEQS	National Environmental Quality Standards
PEQS	Punjab Environmental Quality Standards
PEPA	Punjab Environmental Protection Act
ToRs	Term of references
WAPDA	Water And Power Development Authority

ANNEXURE-Q

GLOSSARY

Glossary:

Words	Dictionary
Discrepancies	A difference between conflicting facts, claims or opinions
Mitigation	The action of lessening in severity or intensity
Evaluated	Estimate or determine the nature, value, quality, ability, extent, or significance of
Legislation	law enacted by a legislative body
Aspects	A distinct feature or element in a problem
Compliance	Acting according to certain accepted standards
Flora	All the plant life in a particular region or period
Fauna	All the animal life in a particular region or period
Screening	The display of a motion picture
Substitutions	An event in which one thing is substituted for another
Regulations	An authoritative rule
Stakeholders	A person or organization with an interest or concern in something
Vulnerable	Susceptible to attack
annunciation	A formal public statement
rehabilitation	The conversion of wasteland into land suitable for use of habitation or cultivation

ANNEXURE-R

STUDY TEAM

Study Team

Sr. No.	Designation	Name/Qualification	Experience
1)	Chief Environmentalist/ Lead Environmental Professional	Abdul Hafeez Nasir PhD Scholar Environmental Management	Ten Years' Experience as Environmentalist
2)	Senior Environmentalist/ Environmental Professional	Iftikhar Ahmed M.Phil Environmental Sciences	Eight Years' Experience as Environmentalist
3)	Environmental professional	Sabeera Tauheed M.phil Environmental Science	3 Years' Experience as Environmentalist
4)	Environmental professional/ Author of the report	Maham Ahsan MS. Environmental Science	1 Year Experience as Environmentalist

ANNEXURE-S

REFERENCES

REFERENCES

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