

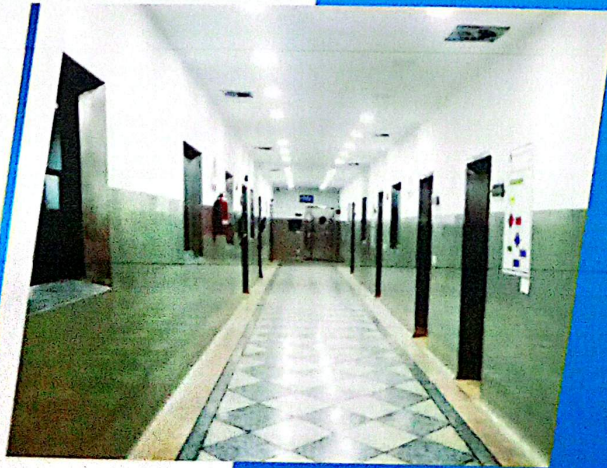
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Environment Impact Assessment 2023

M/S Arreta Pharma
(Pvt) Ltd.

Plot no 13, Street
Industrial Estate, P



EXECUTIVE SUMMARY

This report presents the findings of "Environmental Impact Assessment (EIA)" for the operations of the pre-constructed pharmaceuticals manufacturing unit of M/s Arreta Pharmaceuticals (Pvt) Ltd, RCCI, Industrial Estate, Rawalpindi.

Company has been constructed in 2015-16 as a pharmaceuticals formulation unit but due to fiscal concerns, it has been sale out to current management in 2022. Current management (since August 2022) is keen towards environmental compliance of the company. The proposed facility is located at Plot no 13, Street no. N-5, RCCI, Industrial Estate, Rawalpindi. It is located in designated industrial estate of Rawat, Rawalpindi. M/s Arreta Pharmaceuticals (Pvt) Ltd is formulating healthcare products under DRAP regulations (Drugs Act, 1976), founded in 2016 with Registration No. 000846. Arreta Pharmaceuticals (Pvt) Ltd is committed to good healthcare of the people as per its quality policy statement and endeavoring to upgrade its standards and customer services. The main objective of the company is to make quality healthcare products to make a healthy society.

The EIA study aims at the identification of the possible environmental and social impacts of the operations of formulation plant on its immediate surroundings on both short and long-term basis, suggesting mitigation measures and identifying the responsible agencies to implement those measures. This study has been accomplished in line with the provisions – guidelines and directives of Punjab Environmental Protection Agency.

Outline of the Project/operations

Arreta Pharmaceuticals (Pvt) Ltd intends to operate a pre-constructed Pharmaceutical Manufacturing unit after achieving the approvals from Punjab EPA. Total area of land is 2400sq.ft. The said site lies at Latitude 33.520776 and Longitude 73.248518.

The production process for finished products (DRAP registered) begins with the collection of the right raw materials. Raw material is first placed in quarantine until its analysis and release clearance as per company SOP under the supervision of Quality Assurance department. Arreta Pharmaceuticals (Pvt) Ltd has registered products containing orals (capsules and tablets), dry suspensions, injectable. Raw materials are mixed to make their finished form, then packed, labelled and send to finished good store until final release to market/vendors.

Production has not been started in full swing. Machines are being installed and maintained for trail batches. However, given below are general estimates as per the installed capacity of the machines.

production capacity

1. Dry Suspension: 18000/month
2. Orals (capsules + tablets): 20000/month
3. Injectable: 5000/month

Potential Impacts and Mitigation Measures

Beneficial/Positive Impacts:

The instituting of the said facility will contribute towards;

1. Enhancing Pakistan's domestic productivity, and help diversify Pakistan's economy
2. Provision of employment and stimulation of local economy.
3. Provision of local high quality healthcare products.
4. Provision of better quality of life
5. Contribution towards goal 3 of Sustainable Development Goals i.e., 'Provision of good health care and wellbeing for all' till 2030.
6. Contribution towards goal 8 of Sustainable Development Goals i.e., 'Decent work and economic growth' till 2030
7. Contribution towards goal 9 of Sustainable Development Goals i.e., 'Promoting Industry, Innovation and infrastructure' till 2030
8. Potential of improvement for social and cultural values of local people's exchange of values and standards through positive social interactions.

Potential Environmental impacts

Impacts	Mitigation measures
Construction Phase (no impacts)	
Change of Land use	No construction activity is planned as building is already constructed so 'no impacts' on land-use change have reported
Soil Erosion, Degradation and Contamination	The project site will not experience Soil Erosion, Degradation and Contamination ☐ Facility is located inside the designated industrial estate. ☐ Building is already constructed ☐ No significant increase in traffic flow due to facility operations ☐ There is also no chance of

	fuel/oils/chemicals spillage and leakage from equipment's and vehicles, and inappropriate waste disposal. □ Facility's covered area is fully paved and there is existent mechanism for the disposal of generated liquid and solid waste.
Operational phase (Few potential impacts)	
Surface Water and Groundwater Contamination The project operational activities i.e., formulation process can contaminate the surface water and groundwater when untreated industrial effluents will dispose directly to water bodies nearby or in sewerage system.	Wastewater will be disposed of in the designated sewerage drain after proper treatment through treatment plant. Treatment plant quotation by CEOG Engineering Pvt Ltd. by has been already been approved.
Particulate emissions and generator stack emissions No air emission is likely to be released during operation of the project; except the dust or PM to be produced during floor cleaning and other such operations, which also will not be posing any environmental threat (will not breach the safe standards).	Wet suppression is done to control dust emissions. There is no boiler and generator ins the facility. Generator emissions (planned to acquire in future) will be controlled by providing proper enclosure, tuning and maintenance.
Occupational safety hazards	HSE department with qualified staff is established and operational in the facility; comprised of □ Safety manager □ Consultant Environment □ Safety officers Training regarding safety will be given on the regular basis to workers Workers will be given PPEs Workers will be trained on their usage and importance. Safety infrastructure (extinguishers, fire hydrant

	system, fire blankets, fire alarm system) has been installed to achieve OSHA standards.
Noise Pollution Noise may occur from machines in production and packing sections And poorly maintained machines	The noisy machines are confined to enclosed cubicle as per DRAP requirements with controlled access and PPEs provision. Machines will be properly maintained with proper record maintenance .
Solid waste management	Possible Solid waste of the facility would include; ☐ Pharmaceutical waste Pharmaceutical /special waste includes rejection of tablets, capsules, dry powder suspension or other chemicals are managed by 'incineration'. A contract has been settled between Arreta Pharma and Amson Vaccines and Pharma Pvt Ltd, Islamabad. ☐ Municipal/general solid waste: Recyclables like paper cartons, glass, iron etc. are being sold by a contracted vendor. ☐ Discarded/Rejected raw material will be sent back to supplier.

Environmental Management & Monitoring Plans(EMMP)

The Environmental Management and Monitoring Plan (EMMP) is to minimize the potential environmental impacts due to the project. The EMMP reflects the commitment of Arreta Pharma Pvt. Ltd to safeguard the environment as well as the surrounding population. The EMMP provides a delivery mechanism to address the adverse environmental impacts, to enhance the project's benefits and to introduce standards of best practices to be adopted for operations of the project.

On the basis of the overall impact assessment, more specifically, nature and magnitude of the residual environmental impacts identified during present EIA, it is concluded that Arreta Pharma Pvt. Ltd is likely to cause environmental impacts mainly during its operational phase. As there is no construction activity involved, so management planning will consider the operations of the facility and cover the emissions, noise level, air quality, wastewater quality, solid waste and worker's occupational safety. However, these impacts can be mitigated provided the proposed activities are carried out as mentioned in the report, and the mitigation measures included in this report are completely and effectively implemented.

he project will directly improve employment, affordable healthcare medicines. There re no remaining issues that warrant further investigation. This EIA is considered as dequate for the environmental and social justification of the project.

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1. INTRODUCTION

1.1 Project Background and Overview

The pharmaceutical industry in any country is considered as the mainstay of public health. Looking at the global scenario, the importance given by developing nations to the pharmaceutical sector can be clearly identified by including healthcare and pharmaceutical industry in their health and welfare strategy. The global pharmaceutical market is valued at no less than US\$440 billion, with annual growth of 6%.

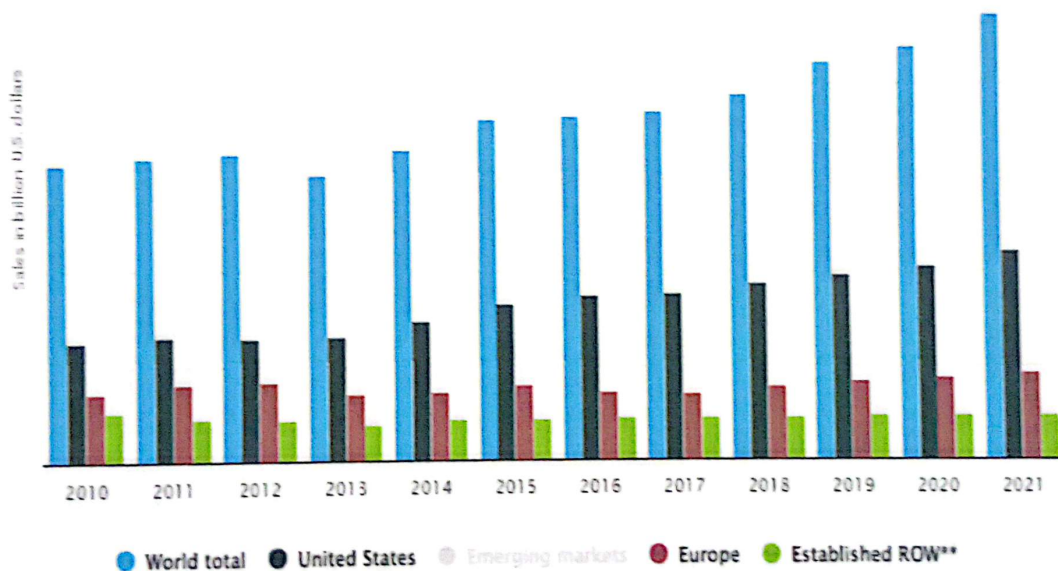


Figure 1.1: Global Pharmaceutical sales from 2017-2021, by region (in billion US dollars).
 Source: <https://www.statista.com/statistics/272181/world-pharmaceutical-sales-by-region>

The pharmaceutical industry is considered the backbone of public health. This is strategically important both for the wellbeing of the population in general and for the provision of good yet affordable healthcare in particular. The low cost of production and the huge potential of this sector has attracted major multinationals to establish their operations and production facilities in Pakistan. Pakistan's Pharmaceutical industry started out slowly but gradually became an integral contributor to the developing economy of Pakistan. At the time of formation, there were only 10 member of Pakistan Pharmaceutical Manufacturers Association (PPMA), as of 2015 there were around 235 companies holding membership. Pharmaceutical industry is one of the most organized industries in Pakistan, employing a large number of professionals in all areas of

operations. Pakistan meets 80% of its domestic demand of medicines from local production and 20% through imports.

The market for pharmaceuticals in Pakistan has been expanding at a rate of around 10 to 15% since last few years. Pakistan is also exporting its surplus drugs to a large number of countries particularly to the Asian and African regions with an expanding trade in the newly emerged Central Asian States. Presently, the pharmaceutical industry in Pakistan is producing all the major pharmaceuticals. There are some special products e.g. immunological, anti-carcinogens, antidiabetics, antidotes and products manufactured from biotechnology, which are still being imported, in the finished form. These specific areas avail the opportunities. Similarly, cancer drugs, provide excellent opportunities for investment. Only few bulk pharmaceutical raw materials are being manufactured locally and most of the pharmaceutical raw materials are being imported in large quantities from different countries of the world. This sector also gives challenge to explore and avail the opportunities.

Pakistan's Pharmaceutical market is very significant in the World market as it is the 10th largest in Asia Pacific and the 4th fastest growing market (2008/09) after China, India & Vietnam. The total worth of Pakistan's Pharmaceutical industry is measured at Rs. 191 Billion (USD 1.8 Billion) in September 2015 most of which is down to private sector investment. The private sector contributes to an overwhelming 82.5% of the total health expenditure. Pakistan, with a local market of 215 million consumers and more than 700 pharmaceutical companies is poised well to gain from opportunities provided under these shifting global patterns of supply and demand.

In the year 2021, exports of pharmaceutical products from Pakistan are estimated to be around \$3.2 billion, doubling from \$1.64 billion in 2011. As stated in the reports. Its total exports in 2019 stood at \$218 million, up from \$44.4 million in 2003. Yet exports from the sector accounted for only 0.9 percent of Pakistan's total export to the world in 2019. Pakistan's Imports of Pharmaceutical products were US\$3.78 Billion in 2021, according to the United Nations COMTRADE database on international trade and most of Pakistan's imports of pharmaceutical products and raw materials come from Germany, Switzerland, France, Belgium, and a handful of other Western nations along with China as well. Again all these imports are payable in foreign exchange and have an impact on the cost of products depending upon exchange rate. Due to recent expansion of public healthcare in the 5th largest global market by size, the value of pharmaceuticals manufactured in Pakistan could rise to USD 5 billion by 2024-25.

Table 1.1: Province based Pharmaceutical units in Pakistan

Area	1999	2017	2019
Punjab	160	370	440
Sindh	101	163	183
KPK	32	98	114
Baluchistan	2	13	15
AJK	9	6	7
Total	304	650	759

The key to the success of Pakistani pharmaceutical companies is based on a simple formula, i.e. the production of high quality products at current Good Manufacturing Practices (cGMP) at most economical rates. Nearly all of Pakistan's leading pharmaceutical companies has maintained high standards to ensure compliance of all operations of production and quality control under the cGMP guidelines. As a result, they are now successfully exporting their products to various international territories.

1.2 Purpose of Report

As per PEPA 2012 and the IEE/EIA Regulation 2000 it is mandatory for the obtain Environmental Approval from EPA Punjab by filing an IEE or EIA as the case may be, proponent of any development project to This Report presents the Environmental Impact Assessment (unit EIA) for aforesaid medicines manufacturing compliant facilities and offering them at the, before the Agency. For this purpose, the proponent has engaged environmental consultant.

The purpose of this study is to identify the environmental baseline i.e. physical, biological and socio economic/cultural conditions and assess all possible impacts arising during the construction and operation phase of the project with the aim to find out appropriate measures for their mitigation, to either eliminate those impacts or to bring them to acceptable level and formulate Environmental Management Plan (EMP) for implementation of the project in environment friendly manner.

The report provides relevant information, as required under the officially approved format, to facilitate issuance of the decision makers i.e. EPA Punjab for the Environmental Approval.

ions. Pakistan meets 80% of its domestic demand of medicines from local production and 20% through imports.

Market for pharmaceuticals in Pakistan has been expanding at a rate of around 10% since last few years. Pakistan is also exporting its surplus drugs to a large number of countries particularly to the Asian and African regions with an expanding trade in the re-emerged Central Asian States. Presently, the pharmaceutical industry in Pakistan is producing all the major pharmaceuticals. There are some special products e.g. biological, anti-carcinogens, antidiabetics, antidotes and products manufactured from technology, which are still being imported, in the finished form. These specific areas provide the opportunities. Similarly, cancer drugs, provide excellent opportunities for investment. Only few bulk pharmaceutical raw materials are being manufactured locally, most of the pharmaceutical raw materials are being imported in large quantities from different countries of the world. This sector also gives challenge to explore and avail the opportunities.

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The report provides relevant information, as required under the officially approved format, to facilitate issuance of the decision makers i.e. EPA Punjab for the Environmental Approval.

3 Brief Description, Nature, Size and Location of the Project

The proposed facility is located at Plot no 13, Street no. N-5, RCCI, Industrial Estate, Rawalpindi. It is located in designated industrial estate of Rawat, Rawalpindi. M/s Arreta Pharmaceuticals (Pvt) Ltd is formulating healthcare products under DRAP regulations (Drugs Act, 1976), founded in 2016 with Registration No.000846

Company has been constructed in 2015-16 as a pharmaceuticals formulation unit but due to fiscal concerns, it has been sold out to current management in 2022. Current management (since August 2022) is keen towards environmental compliance of the company and recruited the HSE staff. Dr. Ilmas (PhD Environmental Sciences)/HOD HSE has been engaged for conducting Environmental Impact Assessment (EIA) of Arreta Pharmaceuticals (Pvt.) Ltd.

Arreta Pharmaceuticals (Pvt) Ltd is committed to good healthcare of the people as per its quality policy statement and endeavoring to upgrade its standards and customer services.

3.1 Location

Site having the coordinates of Latitudes 33.520776 and Longitude as 73. 248518. Location on google map is showing in figure 1.2.

3.2 Area covered

Covered area of the facility is 2400 sq. ft

3.3 Raw materials

Desired raw materials as per the registered products are detailed in annex 2.

3.4 Finished products

List of registered products with DRAP registration numbers is attached in annex 3.

3.5 Production Details

Production has not been started in full swing. Machines are being installed and maintained for trial batches.

However, given below are general estimates as per the capacity of installed machines

Dry Suspension: 18000/month

Orals (capsules + tablets): 20000/month

Injectable: 5000/month

1.4 The Proponent

M/s Arreta Pharmaceuticals (Pvt) Ltd.

Address: Plot no 13, Street no. N-5, RCCI, Industrial Estate, Rawalpindi.

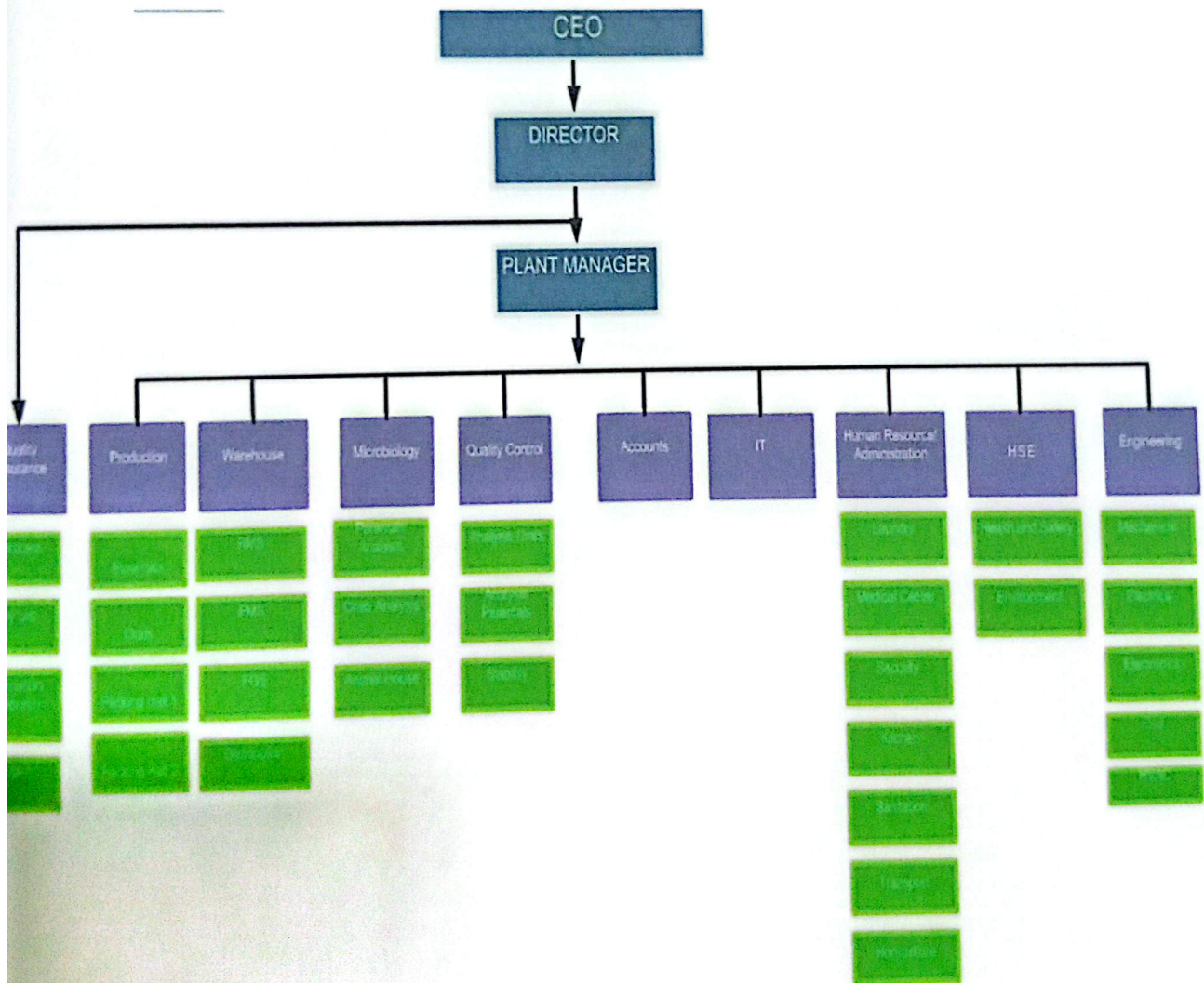
Proponent details:

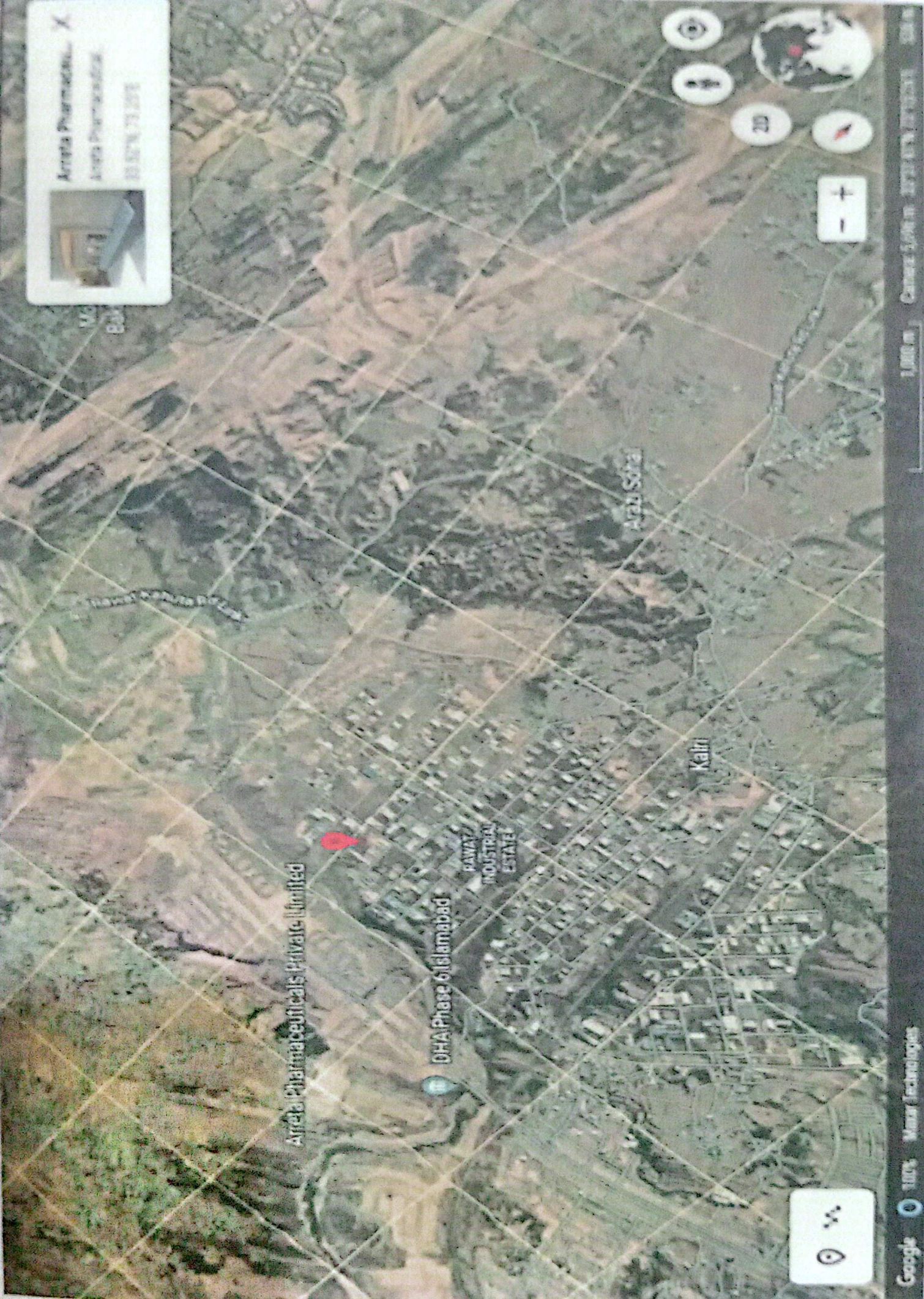
Sajjad Hussain

Chief Executive Officer (CEO)

Contact: + 92 51 4499437

1.5 Organizational Organogram





Arreeta Pharmaceuticals X
Arreeta Pharmaceuticals
33.52°N, 73.20°E

1.6 Details of Consultant

For the preparation of the EIA Report of the said project, the proponent has hired the services of the environmental consultants; Team comprising of environmental consultant, environmental engineers, safety experts have worked on this report. This Team has provided quality services in various environmental sectors i.e.

1. Environmental Assessment Reports i.e. IEE/EIA
2. Environment Management Plans (EMP)
3. Waste Water Treatment Plant (WWTP) Designing
4. WWTP Construction Supervision, Commissioning and Operations
5. Monitoring and inspection
6. Environmental modeling
7. Environmental advisory
8. Designing of occupational health and safety plan

1.6.1 Contact Details

Focal person	Dr. Ilmas
Contact number	03361545408

1.6.2 Team

The following table lists the names of experts involved in the making of EIA report.

Table 1.2: List of Expert

S.NO	Name	Qualification	Role
1	Dr. Ilmas	Ph.D Environmental sciences	Designing , Process detailing ,Site survey and analysis of impacts on surroundings
2	Dr. Sofia Khalid	PhD Environmental biology	Report review
3	Shazaib Malik	MS Environmental Engineering	Socio-economic survey
4	Rashid Malik	IOSH,NEBOSH	Safety gap analysis

Environmental Impact Assessment

Purpose of the Report

The development of any Project leads to positive and adverse changes in environmental and change in social settings of the Project Area. The intensity and level of change, however, depends upon the nature of the Project and the baseline environmental conditions of the area. The development and commencement of said project will cause minor to moderate adverse environmental and social impacts on the surrounding area. Thus, an environmental and social study is mandatory to establish the baseline conditions, evaluate the possible adverse impacts if any, and devise the mitigation measures.

Section 12 of Pakistan Environmental Protection Act, 1997 (PEPA, 1997) states "No proponent of a project shall commence construction or operation unless he has filed with the Provincial Agency an Initial Environmental Examination (IEE) and, where the project is likely to cause an adverse environmental effect, an Environmental Impact Assessment (EIA), and has obtained approval from the Provincial Agency in respect thereof." Later on, Punjab Environmental Protection Agency (Review of IEE and EIA) Regulations, 2000 provided the guidelines for categorizing the Projects.

The main objectives of this EIA study were;

- a. To determine and document the state of the environment of the project area to establish a baseline in order to assess the suitability of the Said Project in that area.
- b. To identify preconstruction, construction and operation activities and assess their impacts on environment.
- c. Provide assistance to the proponent for planning, designing and implementing the project in a way that would improve ecological resilience, strengthen environment, eliminate or minimize the negative impact on the bio physical and socioeconomic environment and maximizing the benefits to all parties in cost effective manner.
- d. To present Mitigation and Monitoring Plan to smoothly implement the suggested mitigation measures and supervise their efficiency and effectiveness.
- e. To provide opportunity to the public for understanding the project and its impacts on the community and their environment in the context of sustainable development.
- f. Prepare an EIA Report for submittal to the Environmental Protection Agency, Punjab for according Environmental Approval

Methodology

A kick off meeting was held with the management of Areeta pharmaceutical and Environmental protection department, Rawalpindi (field) to discuss and clarify issues, objectives, and scope of the study as well as the consultant's approach and methodology.

The following methodology was recommended for purposed project:

- Review of governing legislation and statutory requirements,
- Description of the proposed project,
- Baseline environmental data collection,
- Stakeholder Consultations at various levels (institutional, NGOs, corporate sector and Grass root level i.e. affected peoples),
- Identification of potential environmental impacts,
- Evaluation of the significance of environmental impacts,
- Recommended mitigation measures and monitoring requirements,
- Development of Environmental Management and Monitoring Plan (EMMP)
- Preparation of EIA report

Report structure

This EIA reviews information on existing environmental attributes of the Study Area. Geological, hydrological and ecological features, air quality, noise, water quality, soils, social and economic aspects and cultural resources are included. The report predicts the probable impacts on the environment due to the said project also proposes various environmental management measures.

Details of all background environmental activities, pollution sources, predicted environmental quality and related aspects have been provided in this report.

The structure of the assessment report will be as follow;

Description of the Project

Description of Environmental and Social Conditions

Assessment of Environmental Impacts and Mitigation Measures

- Mitigation Measures for Identified Impacts
- Environmental Management and Monitoring Plan (EMMP)
- Recommendations and Conclusion

1.7.4 Submission and Review of Draft Report

The consultant has submitted one hard and soft copy of the draft report to higher management of Arreta Pharma Pvt Ltd for their review. The objective was to give them an opportunity to review the findings of the study. Ambiguities regarding this study were clarified, and suggestions/ recommendations voiced for inclusion were added in the final report.

1.6.5 Final Report

The consultant reviewed the feedback obtained from the Arreta Pharma Pvt Ltd and all the comments were incorporated in the draft report likewise. One hard and soft copies of the final report were then submitted to Arreta Pharma Pvt Ltd.

2. POLICY, LEGAL AND ADMINISTRATIVE FRAMEWORK

2.1 Introduction

Pakistan being a signatory of multilateral international treaties has a comprehensive set of environmental legislation covering multiple environmental issues facing Pakistan like pollution of freshwater bodies and coastal water, air pollution, deforestation, loss of biodiversity, lack of proper waste management and climate changes. The basic policy and legislative framework along with detailed rules, regulations and guidelines required for the implementation of the policies and enforcement of legislation for the protection of the environment and overall biodiversity are in place.

The compliance status of the operations of the Arreta Pharmaceuticals Pvt Ltd. was reviewed with reference to the legislation and existing legal framework on the environment in Pakistan and International level as described henceforth.

2.2 National Environmental Policy, 2005

The National Environment Policy (NEP) aims to protect, conserve and restore Pakistan's environment in order to improve the quality of life of the citizens through sustainable development. In NEP, the further sectorial guidelines, Energy Efficiency and Renewable directly related to building energy code for newly constructed buildings were introduced. The NEP provides an overarching with a framework for addressing the Environmental issues facing Pakistan, pollution of freshwater bodies and coastal waters, air pollution, lack of proper waste management, deforestation, loss of biodiversity, desertification, natural disasters and climate change. It also provides directions for addressing the cross-sectored issues as well the underline causes of Environmental degradation and meeting international obligations.

The NEP, while recognizing the goals and objectives of National Conservation Strategy, National Environmental Plan and other existing environment-related national policies, strategies and action plans provides broad guidelines to the Federal Government., Provincial Government, Federally Administered Territories and local Government for addressing environmental concerns and ensuring effective management of their environmental resources.

2.3 Laws and Regulations

Pakistan has several laws and regulations regarding the conservation and protection of the environment. However, the enactment of comprehensive legislation on the environment, in the form of an act of parliament, is a relatively new phenomenon. Most of the existing laws on environmental issues were enforced over an extended period of time and are context-specific. The laws relevant to the developmental projects are briefly reviewed below.

2.3.1 Punjab Environmental Protection Act, 1997 (Amended 2012)

After 18th Constitutional Amendment in the Constitution of Pakistan, the Federal Ministry of Environment has been dissolved, and the subject of the environment has been handed over to provinces. The major content of the Punjab Environmental Protection Act is same as of Pakistan Environmental Protection Act (PEPA), 1997. Minor amendments/changes have been made viz.

- The Name of Act has been changed into "Punjab Environmental Protection (Amendment) Act, 2012".
- For the words "Federal Government", wherever occur, the word "Government" shall be substituted;
- For the words "Federal Agency", wherever occur, the words "Provincial Agency" shall be substituted; and
- For the word "National", wherever occurs, the word "Punjab" shall be substituted.

All the other clauses, sub-clauses, sections and sub-sections are almost same.

The Punjab Environmental Protection Act, 1997 (Amended 2012) is the basic legislative tool empowering the Punjab government to frame regulations for the protection of the environment. The Act is applicable to a broad range of issues and extends to air, water, soil, marine and noise pollution, as well as the handling of hazardous waste.

The discharge or emission of any effluent, waste, air pollutant or noise in an amount, concentration or level in excess of the Punjab Environmental Quality Standards (PEQS) specified by the Punjab Environmental Protection Agency (Punjab EPA) has been prohibited under the Act, and penalties have been prescribed for those contravening the provisions of the Act.

The requirement for environmental assessment is laid out in Section 12 (1) of the Act. Under this section, "no proponent of a project shall commence construction or operation unless he has filed with the Provincial Agency an initial environmental examination or where the project is likely to cause an adverse environmental effect, an environmental impact assessment, and has obtained from the Provincial Agency approval in respect thereof".

Section 12(6) of the act states that this provision is applicable only to such categories of projects as Punjab Environmental Protection Agency (Review of IEE and EIA Regulations), 2012.

2.3.2 Pakistan Environmental Protection Agency (Review of IEE and EIA Regulations), 2000

Pakistan Environmental Protection Agency (Review of IEE and EIA Regulations), 2000 (the Regulations) prepared by the Punjab Environmental Protection Agency under the powers conferred upon it by the Act, provide the necessary details on preparation, submission and review of the IEE and the EIA. Categorization of projects for IEE and EIA is one of the main components of the regulations.

Projects have been classified on the basis of the expected degree of adverse environmental impacts. Project types listed in Schedule-I are designated as potentially less damaging to the environment and those listed in Schedule-II as having potentially serious adverse effects. Schedule-I projects require an IEE to be conducted, provided they are not located in environmentally sensitive areas. For the schedule-II projects, conducting an EIA is necessary. Salient features of the regulation, relevant to the proposed project are listed below:

Categories of projects requiring IEE and EIA are issued through two schedules attached to the Regulations.

- A fee, depending on the cost of the project, has been imposed for review of EIA and IEE.
- The submittal is to be accompanied by an application in prescribed format included as schedule V of the Regulations.
- The EPA Punjab is bound to conduct preliminary scrutiny and reply within 10 days of submittal of the report a) confirming completeness, b) asking for additional information, or c) requiring additional studies.
- The EPA Punjab is required to make every effort to complete the review process for IEE within 45 days and of the EIA within 90 days, of the issue of confirmation of completeness.
- EPA Punjab accords their approval subject to following conditions:
- Before commencing construction of the project, the proponent is required to submit an undertaking accepting the conditions.
- Before commencing operation of the project, the proponent is required to obtain from EPA Punjab a written confirmation of compliance with approval conditions and requirements of the IEE/ EIA.
- An EMP is required to be submitted with the request for obtaining confirmation of compliance.
- The EPA Punjab are required to issue a confirmation of compliance within 15 days of receipt of the request and complete documentation.

The IEE/EIA approval will be valid for three years from the date of the accord.

A monitoring report is required to be submitted to the EPA Punjab after completion of construction, followed by annual monitoring reports during operations.

This (operations of Pharmaceuticals industry) project falls in Schedule-II of the regulations. Hence, this type of project needs an EIA to be conducted.

2.3.3 Punjab Environmental Quality Standards (PEQS)

The PEQS, promulgated under the PEPA 1997 (Amended 2012), specify the following standards:

The maximum allowable concentration of pollutants (16 parameters) in gaseous emissions from industrial sources.

- For power plants operating on oil and coal:
- Maximum allowable emission of Sulphur dioxide,
- The maximum allowable increment in the concentration of sulfur dioxide in the ambient air,
- The maximum allowable concentration of nitrogen oxides in ambient air, and
- Maximum allowable emission of nitrogen oxide for steam generators as a function of heat input.
- The maximum allowable concentration of pollutants (32 parameters) in municipal and liquid industrial effluents discharged to inland waters, sewage treatment and sea (three separate set of numbers).

The PEQS for liquid effluents discharged to inland waters, gaseous emission from industrial sources and emissions from motor vehicles are provided as on the following website. Website: http://epd.punjab.gov.pk/rules_regulations

The Punjab Environmental Quality Standards (PEQS) specify the following standards:

- The maximum allowable concentration of pollutants (32 parameters) in municipal and liquid industrial effluents discharged into inland waters, sewage treatment facilities, and the sea (three separate sets of numbers).
- Maximum allowable concentration of pollutants (16 parameters) in gaseous emissions from industrial sources.
- Maximum allowable concentration of pollutants (02 parameters) in gaseous emissions from vehicle exhaust and noise emission from vehicles.
- Maximum allowable noise levels from vehicles.
- Ambient Noise and Air Quality Standards.

These standards also apply to the gaseous emissions and liquid effluents generated by the generator, process waste etc. The standards for vehicles will apply during the construction as well as operation phase of the project. Standards for air quality have not been prescribed as yet.

2.3.4 PEQS for Liquid Effluent

The Punjab Environmental Quality Standards (PEQS) for the discharge of effluent from industry are presented in Table 2.1.

Table 2.1: PEQS for Liquid Effluent Discharge		
Parameters	Into Inland Waters	Into Sewage Treatment
Temperature	$\leq 3^{\circ}\text{C}$	$\leq 3^{\circ}\text{C}$
pH Value	6-9	6-9
Biological Oxygen Demand (BOD) ₅ at 20°C	80	250
Chemical Oxygen Demand (COD)	150	400
Total Suspended Solids (TSS)	200	400
Total Dissolved Solids (TDS)	3500	3500
Grease and Oil	10	10
Phenolic Compounds (as phenol)	0.1	0.3
Chlorides (as Cl')	1000	1000
Fluoride (as F')	10	10
Cyanide (CN') total	1.0	1.0
An-ionic Detergents (as MBAs)	2.0	20
Sulphate (SO'')	600	1000
Sulphide (S ²⁻)	1.0	1.0
Ammonia (NH ³)	40	40
Pesticides	0.15	0.15
Cadmium (Cd)	0.1	0.1

Chromium (trivalent and hexavalent)	1.0	1.0
Copper (Cu)	1.0	1.0
Lead (Pb)	0.5	0.5
Mercury (Hg)	0.01	0.01
Selenium (Se)	0.5	0.5
Nickel (Ni)	1.0	1.0
Silver (Ag)	1.0	1.0
Total Toxic Metals	2.0	2.0
Zinc (Zn)	5.0	5.0
Arsenic (As)	1.0	1.0
Barium (Ba)	1.5	1.5
Iron (Fe)	8.0	8.0
Manganese (Mn)	1.5	1.5
Boron (B)	6.0	6.0
Chlorine (Cl ₂)	1.0	1.0

Source: PEQS, Punjab Environmental Protection Agency

2.3.5 PEQS for Gaseous Emission

The Punjab Environmental Quality Standards (PEQS) for permissible limits of gaseous emission from industry are presented in Table 2.2.

Table 2.2: PEQS for Gaseous Emission

Parameter	Source of Emission	Standard
Smoke	Smoke opacity not to exceed	40% or less on Ringleman Scale or equivalent smoke number
Particulate Matter	Boilers and Furnaces:	300
	Oil Fired	500
	Coal Fired	1000

	Grinding, crushing, clinker coolers and related processes, metallurgical processes, converters, blast furnaces and cupolas	
Hydrogen Chloride	Any	400
Chlorine	Any	150
Hydrogen Fluoride	Any	150
Hydrogen Sulphide	Any	10
Sulphur Oxides	Sulfuric Acid/sulphonic Acid Plants	5000
	Other Plants except power plants operating an oil and coal	1700
Carbon Monoxide	Any	800
Lead	Any	50
Mercury	Any	10
Cadmium	Any	20
Arsenic	Any	20
Copper	Any	50
Antimony	Any	20
Zinc	Any	200
Oxides of Nitrogen	Nitric Acid Manufacturing Unit	3000
	Other plants except for power plants operating on oil or coal:	
	Gas fired	400
	Oil fired	600
	Coal-fired	1200

Source: PEQS, Punjab Environmental Protection Agency

2.3.6 PEQS for Vehicular Emission

The Punjab Environmental Quality Standards (PEQS) for permissible limits of emissions from vehicles are presented in Table 2.3.

Table 2.3: PEQS for Vehicular Emission

Parameters	Standards (Maximum permissible limits)	Measuring Method
Smoke	40% or 2 on the Ringleman Scale During engine acceleration mode	To be compared with Ringleman chart at a distance of 6 meters or more
Carbon Monoxide	6%	Under idling conditions: non-dispersive infrared detection through the gasanalyser.
Noise	85 dB (A)	A sound meter at 7.5 meters from the source

Source: PEQS, Punjab Environmental Protection Agency

2.3.7 PEQS for Drinking Water, 2010

The Punjab Environmental Quality Standards (PEQS) for drinking water quality, 2010 are presented in Table 2.4.

Table 2.4: PEQS for Drinking Water Quality

Parameter	Standard values	WHO standards
Biological		
All water intended for drinking (E. Coli or Thermo-tolerant Coliform bacteria)	Must not be detectable in any 100 ml sample.	Must not be detectable in any 100 ml sample.
Treated water is entering the distribution system (E. Coli or Thermo-tolerant Coliform and total Coliform bacteria)	Must not be detectable in any 100 ml sample.	Must not be detectable in any 100 ml sample.
Treated water in the distribution system (E. Coli or Thermo-tolerant Coliform and total Coliform bacteria)	Must not be detectable in any 100 ml sample. In case of large supplies, where sufficient samples are examined, must not be present in 95% of the samples taken throughout any 12-month period.	Must not be detectable in any 100 ml sample. In case of large supplies, where sufficient samples are examined, must not be present in 95% of the samples taken throughout any 12-month period.

cal	≤ 15 TCU	≤ 15 TCU
	Non-acceptable	Non-acceptable
r	Non-acceptable	Non-acceptable
idity	< 5 NTU	< 5 NTU
hardness	< 500 mg/L	—
	< 1000	< 1000
	6.5- 8.5	6.5- 8.5
nical		
ntial Organic	mg/Litre	mg/Litre
inium	≤ 0.2	0.2
nony	≤ 0.005	0.02
nic	≤ 0.05	0.01
um	0.7	0.7
on	0.3	0.3
nium	0.01	0.003
ride	≤ 250	250
mium	≤ 0.05	0.05
per	2	2
c Inorganic		mg/Litre
nide	≤ 0.05	0.07
ride	≤ 1.5	1.5
d	≤ 0.05	0.01
agnese	≤ 0.5	0.5
cury	≤ 0.001	0.001
cel	≤ 0.02	0.02
ate	≤ 50	50
ite	≤ 3	3
c	5	3
sticides mg/L		PSQCA No.4639- 2004.page No 4 Table No. 3serial No. 20-58 < 0.002 0.01
enolic Compounds		
lynuclear aromatic		
drocarbons		
dioactive		0.1
pha emitters bq/L	0.1	1
ta emitters	1	

Source: PEQS, Punjab Environmental Protection Agency

2.8 PEQS for Ambient Air and Noise
The Punjab Environmental Quality Standards (PEQS) for Ambient Air and Noise, 2016
are presented in Table 2.5 and 2.6.

Table 2.5: PEQS for Ambient Air

Pollutants	Time Weighted Average	Concentration in Ambient Air ($\mu\text{g}/\text{m}^3$)
Sulfur Dioxide (SO_2)	Annual Average*	80
	24 hrs**	120
Oxides of Nitrogen gas (NO)	Annual Average*	40
	24 hrs**	40
Oxides of Nitrogen gas (NO_2)	Annual Average*	40
	24 hrs**	80
Ozone (O_3)	1 hour	130
Suspended Particulate Matter (SPM)	Annual Average*	360
	24 hrs**	500
Respirable Particulate Matter (PM_{10})	Annual Average*	120
	24 hrs**	150
Respirable Particulate Matter ($\text{PM}_{2.5}$)	Annual Average*	15
	24 hrs**	35
	1 hr	15
Lead (Pb)	Annual Average*	1
	24 hrs**	1.5
Carbon monoxide (CO)	8 hrs	5 mg/m^3
	1 hr	10 mg/m^3

** Annual Arithmetic mean of minimum 1040 measurements in a year taken twice a week 24 hourly at a uniform interval

* 24 hourly / 8 hourly values should be met 98 % of the year, 2 % of the time, it may exceed.

Source: PEQS, Punjab Environmental Protection Agency

Table 2.6: PEQS for Noise

Category of Area/ Zone	Limits in dB(A) Leq	
	Daytime	Night time
Residential area	55	45
Commercial area	65	55
Industrial area	75	65
Silence area	50	45

Source: PEQS, Punjab Environmental Protection Agency

2.3.9 National Drinking Water Supply 2009

During September 2009 the government approved the National Drinking Water Policy that provides a framework for addressing the key issues and challenges facing Pakistan in the provision of safe drinking water to the people by 2025.

Drinking water is the constitutional responsibility of the provincial governments, and the specific provision function has been devolved to specially created agencies in cities and Towns and Tehsil Municipal Administrations under the Local Government Ordinance 2001.

Therefore, this policy framework is intending to guide and support the provincial and district governments in discharging their responsibility in this regard. The overall goal of the national drinking water policy is the following:

- To ensure safe drinking water to the entire population at an affordable cost in an equitable, efficient and sustainable manner
- To ensure a reduction in the incidence of mortality and morbidity caused by water-borne diseases.

The policy is expected to be reviewed and updated every five years to examine its implementation and efficacy and to adapt it to the changing situation in the country

2.3.10 National Sanitation Policy

The National Sanitation Policy aims at providing adequate sanitation coverage for improving the quality of life of the people of Pakistan and to provide physical environment necessary for a healthy life. The Policy can be reached at <http://waterinfo.net.pk/sites/default/files/knowledge/National%20Sanitation%20Policy%202006.pdf>

2.3.11 Punjab Wildlife (Protection, Preservation, Conservation and Management) (Amendment) Act, 2007

The Punjab Wildlife (Protection, Preservation, Conservation and Management) is an act that provides protection, preservation, conservation and management of wildlife in the Punjab Province.

The main aim of this act is the preservation and conservation of wildlife, for sustainable development to comply with the concept of national parks internationally.

2.3.12 Forest Act, 1927

The Act authorizes Provincial Forest Departments to establish forest reserves and protected forests. The Act prohibits any person to set a fire in the forest, quarry stone, remove any forest-produce or cause any damage to the forest by cutting trees or clearing up area for cultivation or any other purpose. Much like the Punjab Wildlife Act described above, the Forest Act is also not likely to be applicable to the proposed project. No project activities will, however, be carried out in any protected forests, and

no unauthorized tree cutting will be carried out for any facility expansion or waste disposal.

2.3.13 Punjab Local Government Ordinance, 2012

This ordinance, which is based upon the Punjab Local Government Ordinance of 2001 promulgated under the devolution plan, defines the roles of the district governments and also addresses the land use, conservation of natural vegetation, air, water and land pollution, disposal of solid waste and wastewater effluents, as well as matters relating to public health – aspects that are relevant to the proposed project.

2.3.14 Land Acquisition Act, 1894

The Land Acquisition Act (LAA) of 1894 amended from time to time has been the de-facto policy governing land acquisition and compensation in the country. The LAA is the most commonly used law for acquisition of land and other properties for development projects. It comprises of 55 sections pertaining to area notifications and surveys, acquisition, compensation and apportionment awards and disputes resolution, penalties and exemptions.

2.3.16 Antiquity Act, 1975

The Antiquities Act of 1975 ensures the protection of cultural resources in Pakistan. The act is designed to protect antiquities from destruction, theft, negligence, unlawful excavation, trade and export. Antiquities have been defined in the Act as ancient products of human activity, historical sites, or sites of anthropological or cultural interest, national monuments, etc.

The law prohibits new construction in the proximity of protected antiquity and empowers the Government of Pakistan to prohibit excavation in an area that may contain articles of archaeological significance.

Under the Act, the project proponents are obligated to:

- Ensure that no activity is undertaken in the proximity of protected antiquity, and
- If during the project an archaeological discovery is made, it should be reported to the Department of Archaeology, Government of Pakistan.

2.3.17 Cutting of Trees (Prohibition Act), 1975

Section 3 of this Act states "No person shall, without the prior written approval of the local formation commander or an officer authorized by him in this behalf, cut fell or damage or cause to cut, fell or damage any tree."

2.3.18 Protection of Trees and Bush wood Act, 1949

This Act prohibits cutting or chopping of trees and bush wood without permission of the Forest Department.

2.3.19 Pakistan Explosive Act, 1884

This Act provides regulations for the handling, transportation and use of explosives during quarrying, blasting and other purposes. The transmission line tower installation may need blasting at rocky/mountainous areas. Thus these regulations will be applicable to the proposed project.

2.3.20 Employment of Child Act, 1991

Section 3, Prohibition of Employment, of this Act starts "No child shall be employed or permitted to work in any of the occupations set forth in Part I of the Schedule or in any workshop wherein any of the processes set forth in Part II of that Schedule is carried on: Provided that nothing in this section shall apply to any establishment wherein such process is carried on by the occupier with the help of his family or to any school established, assisted or recognized by Government."

The Employment of Child Act, 1991 is available at

http://www.na.gov.pk/uploads/documents/1335242011_887.pdf

2.3.21 Factories Act, 1934

The clauses relevant to the proposed project are those that address the health, safety and welfare of the workers, disposal of solid waste and effluents, and damage to private and public property. The Act also provides regulations for handling and disposing toxic and hazardous substances. The Pakistan Environmental Protection Act, 1997 (discussed above), supersedes parts of this Act pertaining to the environment and environmental degradation.

2.3.22 Pakistan Penal Code, 1860

This outlines the penalties for violations concerning pollution of air, water bodies and land. Sections 272 and 273 of this Act deal with the adulteration of food or drink. Noise pollution has been covered in Section 268, which defines and recognizes noise as a public nuisance. "A person is guilty of a public nuisance who does any act or is guilty of an illegal omission which causes any common injury, danger or annoyance to the public or to the people in general who dwell or occupy property in the vicinity, or which must necessarily cause injury, obstruction, danger or annoyance to persons who may have occasion to use any public right."

The code deals with the offences where public or private property or human lives are affected due to intentional or accidental misconduct of an individual or organization. The code also addresses control of noise, noxious emissions and disposal of effluents. Most of the environmental aspects of the code have been superseded by the Pakistan Environmental Protection Act, 1997.

2.3.23 Institutional Set Up

The apex environmental body in the country is the Pakistan Environmental Protection Council (PEPC), presided by the Chief Executive of the Country. Other bodies include

the Pakistan Environmental Protection Agency (Pak-EPA), provincial EPAs (for four provinces, AJK and Gilgit-Baltistan), and environmental tribunals.

The EPAs were first established under the 1983 Environmental Protection Ordinance; the PEPA 1997 further strengthened their powers. The EPAs have been empowered to receive and review the environmental assessment reports (IEEs and EIAs) of the proposed projects and provide their approval (or otherwise).

2.3.24 Environmental Protection Agency's Environmental Guidelines

The Pak EPA has prepared a set of guidelines for conducting environmental assessments. The package of regulations, of which the guidelines form a part, includes the PEPA 1997 and the NEQS. The guidelines themselves are listed below:

- Guidelines for the Preparation and Review of Environmental Reports,
- Guidelines for public consultation,
- Guidelines for Sensitive and Critical Areas, Sectorial Guidelines.

It is stated in the Pakistan Environmental Protection Agency (Review of IEE and EIA) Regulations, 2000 that the EIA or IEE must be prepared, to the extent practicable, in accordance with the Pakistan Environmental Protection Agency guidelines.

The government of Pakistan has also framed guidelines for the preparation of IEE of Projects in various developmental sectors.

2.4 The implication of Legislations to the project

As per Review of Initial Environmental Examination (IEE) and Environmental Impact Assessment (EIA) Regulations, 2000 the Said Medicines Manufacturing Unit falls under B (2) Category of projects "Manufacturing and processing" mentioned in Schedule II requiring EIA.

Arreta Pharmaceuticals Pvt Ltd. being the proponent of the project will ensure that, to all operational phases of the project be carried out in accordance with the EIA report and Environmental Management Plan is effectively implemented. The project will be subjected to four basic provisions relating to pollution control under the Punjab Environmental Protection Act, 1997 (Amended 2012), as contained in section 11, 13, 14 and 15 as follows:

- Section 11, prohibits discharge or emission of any effluent or waste or air pollutant or noise in excess of the PEQS, or the established ambient standards for air, water or land.
- Section 13, prohibits of hazardous wastes.
- Section 14, prohibits the handling of hazardous substance except under license or in accordance with the provision of any local law or international agreement.

3. PROJECT DESCRIPTION

3.1 Introduction

This Chapter provides description of various components of the proposed project and their salient features, location, and phases.

3.2 Type and Category of the Project

According to the Pakistan Environmental Protection Act, 1997, section 12 (1)

"No proponent of a project shall commence construction or operation unless he has filed with the Government Agency designated by Federal Environmental Protection Agency or Provincial Environmental Protection Agencies, as the case may be, or, where the project is likely to cause an adverse environmental effects an environmental impact assessment, and has obtained from the Government Agency approval in respect thereof."

According to the Pakistan Environmental Protection Agency (Review of IEE and EIA Regulations) 2000:

"Pharmaceuticals manufacturing units/industries are included in the projects of Schedule II, List of projects requiring an Environmental Impact Assessment(EIA)."

Thus, the proposed project falls under the category of Schedule II as per IEE/EIA regulations 2000 and requires an EIA to be conducted.

3.3 Objective of the Project

The overarching objective of the proposed project is the production of healthcare medicines. Production of affordable and quality medicines is vital to improve patients' quality of life, allowing them the freedom to live healthier and more fulfilled lives. Pharma industry due to its significant GDP also contributing in the country economy.

Project Location and Accessibility

Facility is located in Rawat Industrial estate (Latitude:33.520776 and Longitude:73.248518). The surrounding areas near the RCCI Industrial estate are shown in Figure 3.1. Rawalpindi Chamber of Commerce & Industry (RCCI) had been striving since 1982 to establish an Industrial Estate in Potohar basically to promote industrial growth and create job opportunities for the local residents. It was in 1988 that the Government of Pakistan announced industrial incentives to encourage

industrial growth in rural areas of the country. The RCCI proceeded to give impetus to the project of establishment of an Industrial Estate in 1992 envisaging early industrial growth under the then industrial policy.

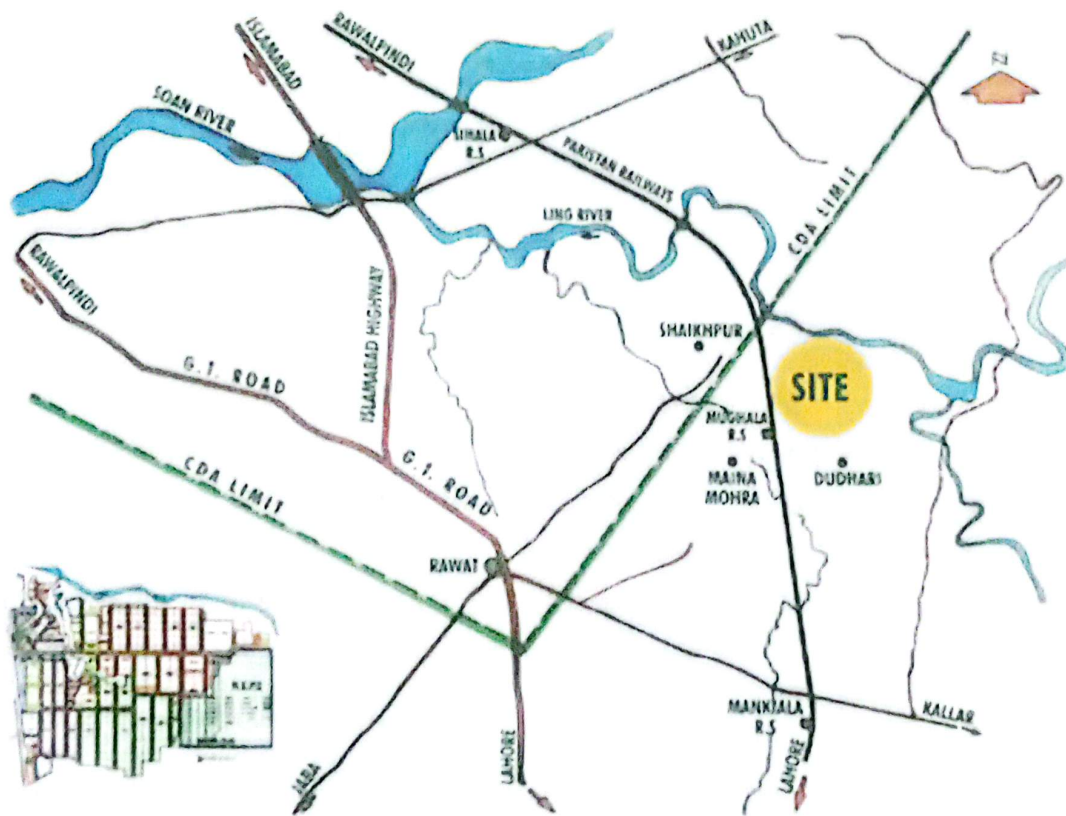


Figure 3.1: Geographic location of RCCI industrial estate

North: Ling streams; The Ling Stream flows in the Potohar region of Northern Pakistan. It starts in the foothills of the Letharar area near Kahuta and, flowing and cutting its way through the hilly area, it meets the Swan River near Sihala. The road that joins Islamabad and Azad Kashmir passes it twice.

South: Islamabad express highway

East: T-Chowk, GT Road

West: DHA Phase-5

5 Site Alternatives

Selected site is surrounded by other industries and no other alternative site is considered for said Project. The site is well located in regard to the following:

1. Within vicinity of existing unit
2. Plot near other industries
3. Easy road access to the market
4. No settlements in close vicinity
5. No watercourse within a safe distance
6. No ecologically sensitive or declared protected area within safe radius of the selected site

In view of these facts, it can be concluded that the industry site is best suited for the project, and will not pose any adverse impact or threat on any component of the environment. Considering the facts that said site is at a safe distance from sensitive receptors. The said site has advantage of not only to be environment friendly but also potentially sound to enhance sustainable development in the region. Therefore, given site is the most suitable for establishment of said project.

3.6 Process/Technology Alternative

Keeping in view all the environmental consideration the project site is located in an industrial area using the best suitable technology for air emission and for the treatment of wastewater. Best suited technology has been proposed for the said project including no air emission. Water mitigation techniques also considered at their best including biochemical treatment for wastewater treatment.

3.7 Environmental Alternative

The unit site is located in an area which is devoid of any biodiversity including forestry, wildlife, migratory birds, game reserves (flora and fauna), or protected species of fauna & flora; fishery or aquatic biology; watershed. There is no cultural or any other heritage in the project area. Summarily, there is no environmental sensitivity in the project area. These factors are also strongly supportive of the proposed project site.

Economic Alternative

ated land is under ownership of proponent and no cost is required to purchase other so it is viable and economic option for proponent. The cumulative effect of this type project would result in noticeable economic growth. The project will also make a live consideration to the industrial growth of the country with quality healthcare ucts.

Vegetation Features of Site

ious local plants are grown at the project site in the open areas, and along the ndary.

Restoration and Rehabilitation Plans

e wouldn't require any construction work at the site as facility building is already ructed. There exists no human settlement within safe radius of the existing project o be displaced owing to the commencement of the said Project. No structure of any ificance stands at the site to be relocated or dismantled. Nearest residence is DHA 5, ocates at 15 km from project site.

Government Approvals

rent approvals/certifications are attached in annexure 4

DESCRIPTION OF THE PROJECT

1.1 Raw Material

material list is attached in annexure.

1.2 Finished Products

ta Pharmaceuticals (Pvt.) Ltd. is involved in manufacturing of many Finished rmaceutical Products, the list of which is attached in annexure 3.

3.12.3 General processing

Generalized procedure for manufacturing of pharmaceutical finished products is given below:

i. Receiving Bay and Deducting Area

The raw material, both active and inactive is received in receiving bay and dusting is done to remove any dust from packs to avoid any contamination.

ii. Quarantine area

Quarantine area is classified into three sections via three different color boundaries including yellow, red and green lines. Yellow boundary line area is for the raw material which is under quality control testing, while green line area is for the raw materials which have been released by quality control department for manufacturing. Red boundary line area is for those raw materials which have been rejected by quality control department and should not be used in manufacturing, which will be sent back to company from where purchased. The raw materials, in their final containers are transferred to quarantine area of yellow boundary 1st until they are under testing by quality control department. Once it gets released by quality control department, it is shifted to green colored line boundary area for use in manufacturing process of syrups. The temperature and humidity is controlled properly and maintained at a temperature of $25 \pm 5^{\circ}\text{C}$ and humidity of $55 \pm 5\%$. Separate rooms are provided for storage of active ingredients and inactive ingredients. Regular temperature and humidity testing is conducted in these storage rooms. Relative Humidity of 45 and Temp of 25°C is being maintained.

iii. Sampling area

Sampling area is the specified area with proper air circulation via HVAC system. In this area, the raw materials are selected by random sampling under the supervision of qualified pharmacist. Samples are taken from upper, medium and bottom layer of containers and are supplied to quality control department for testing of raw material. Once the raw material has been approved and released by quality control department for manufacturing, it is transferred to dispensing area.

Dispensing area

Released raw materials, both active and inactive ingredients by quality control department are dispensed in this section using digital weighing balances under supervision of pharmacist. These are dispensed and are transferred to manufacturing areas.

Manufacturing area

Manufacturing area contains machinery according to the product to be manufactured. The active and inactive raw materials are transferred to manufacturing tank and RO water is added in RO water tank from where it is supplied to manufacturing tanks via some pipes. Automatic Mixing is done to prepare homogeneous solutions. In process samples are taken and supplied to quality control department. Once released the manufactured product is transferred to storage tank until filled, labeled and packed.

i. Washing and drying area

In washing area, the vials are washed along with caps using RO water. These washed bottles are then sterilized and oven dried at 250 °C to remove any dust or any particulate matter.

ii. Filling area

Filling area contains syrup/suspension filling machines. While for tablets and capsules, they are packed in blisters or strips. Once the samples get approved by quality control department, they are transferred for labeling and packaging.

ii. Labelling area

In labeling section, the various manufacturing details are printed onto the primary package like batch number, date of manufacturing, maximum retail price of the therapeutic, etc. as required by Drugs Act.

ix. Packaging area

Pharmaceutical manufacturers have to pack their medicines before they can be sent out for distribution. The type of packaging will depend on the formulation of the medicine.

'ter packs' are a common form of packaging used for a wide variety of products. They are safe and easy to use and they allow the consumer to see the contents without opening the pack.

Primary packaging is the material that first envelops the product and holds it. This usually is the smallest unit of distribution or use and is the package which is in direct contact with the contents. Secondary packaging is outside the primary packaging – perhaps used to group up primary packages together. Tertiary packaging is used for bulk handling, warehouse storage and transport shipping. The most common form is a palletized unit load that packs directly into containers. Some of the primary packed bottles/ blisters are supplied to quality control department for in process quality control testing to check label and its specifications. Once approved these bottles/blisters are then packed into secondary packaging materials i.e. cartons and are stored in finished goods area till they are dispatched in market.

3. Suspension manufacturing

Suspensions are an important class of pharmaceutical dosage forms. The manufacturing of pharmaceutical suspensions involves several steps. The first step is to obtain particles of the proper size typically in the micrometer range. Pharmaceutical suspensions are usually prepared either by direct incorporation/ dispersion method or by precipitation method.

Direct Incorporation method involves following steps:

- Dissolution of the soluble components in the appropriate volume of diluent (vehicle).
- Dispersion of the solid therapeutic agent into the vehicle with the aid of mixing, prior to correction for volume.

The preparation of suspensions by precipitation method is as follows:

- The drug is dissolved in the vehicle (or a portion of the available volume), prior to precipitation following the addition of a counter ion; the salt formed is insoluble

(such systems are frequently deflocculated and are therefore mixed at low shear rates).

- The excipients are then dissolved in the vehicle, or dissolved in a portion of the vehicle, which is then added to the suspension of drug. At this stage, the formulation may be exposed to high shearing rates to ensure homogeneity.
- The volume of the formulation is then corrected by adding the required mass of diluent.

Dry powder injectable manufacturing

a. Dispensing

Calculate the required quantities of the sterile powdered material as per the required batch size against that calculated in master formulation for cross reference. The Active raw materials are weighed based on potency adjustment and moisture content for which a factor is calculated and multiplied with the quantity as claimed in the registration letter.

Check & prepare the dispensing area; it should be clean, humidity and temperature should be according to prescribed parameters. Temperature should not exceed 30°C and relative humidity should not exceed 40%. Make sure that the dispensing area does not contain raw materials other than those that are to be dispensed.

Get line clearance from Quality Assurance officer; the points that need to be checked by QA officer are temperature, relative humidity, cleanliness, equipment calibration, material labeling and storage condition.

After getting the line clearance from QA officer the materials are dispensed in the presence of a dispensing officer and QA officer. Make sure that the bags or containers in which the dispensed materials are kept are properly labeled and the material is dispensed from and in the right container.

For light and moisture sensitive materials a separate dispensing booth is used which is equipped with dehumidifier and a light repellent glass material that prevents the material degradability and similarly separate carbon black containers or bags are used for dispensing such materials.

Similarly, for sterile materials and antibiotics special precautions and separate dispensing areas are available.

Once all the materials are dispensed and properly sealed in the presence of QA officer the dispensing officer transfers the raw materials to the production officer by cross checking each raw material labeling and weight.

The dispensed materials are transferred to the manufacturing area where they are stored under appropriate conditions until a line clearance for aseptic filling is allowed by QA officer.

b. Aseptic Filling & Sealing

Check & prepare the manufacturing area; it should be clean, humidity and temperature should be according to prescribed parameters. Temperature should not exceed 30 C and relative humidity should not exceed 40%. Make sure that the manufacturing area does not contain raw materials other than the desired product to be manufactured.

Get line clearance from Quality Assurance officer; the points that need to be checked by QA officer are temperature, relative humidity, cleanliness, equipment calibration, material labeling and storage condition.

Adjust the physical parameters, like average weight, and intimate QA/QC for test analysis and release for filling. After getting release for filling and sealing proceed with the process and keep on checking the vial weight on intervals.

Initially weight 10 Vials individually, and then average of 5 Vials after each 1 hour. Once the aseptic filling is completed add the data in Record Sheet and reconcile the batch.

After filling and sealing has been completed intimate QA for product sampling and send the sample to QC for release for packing.

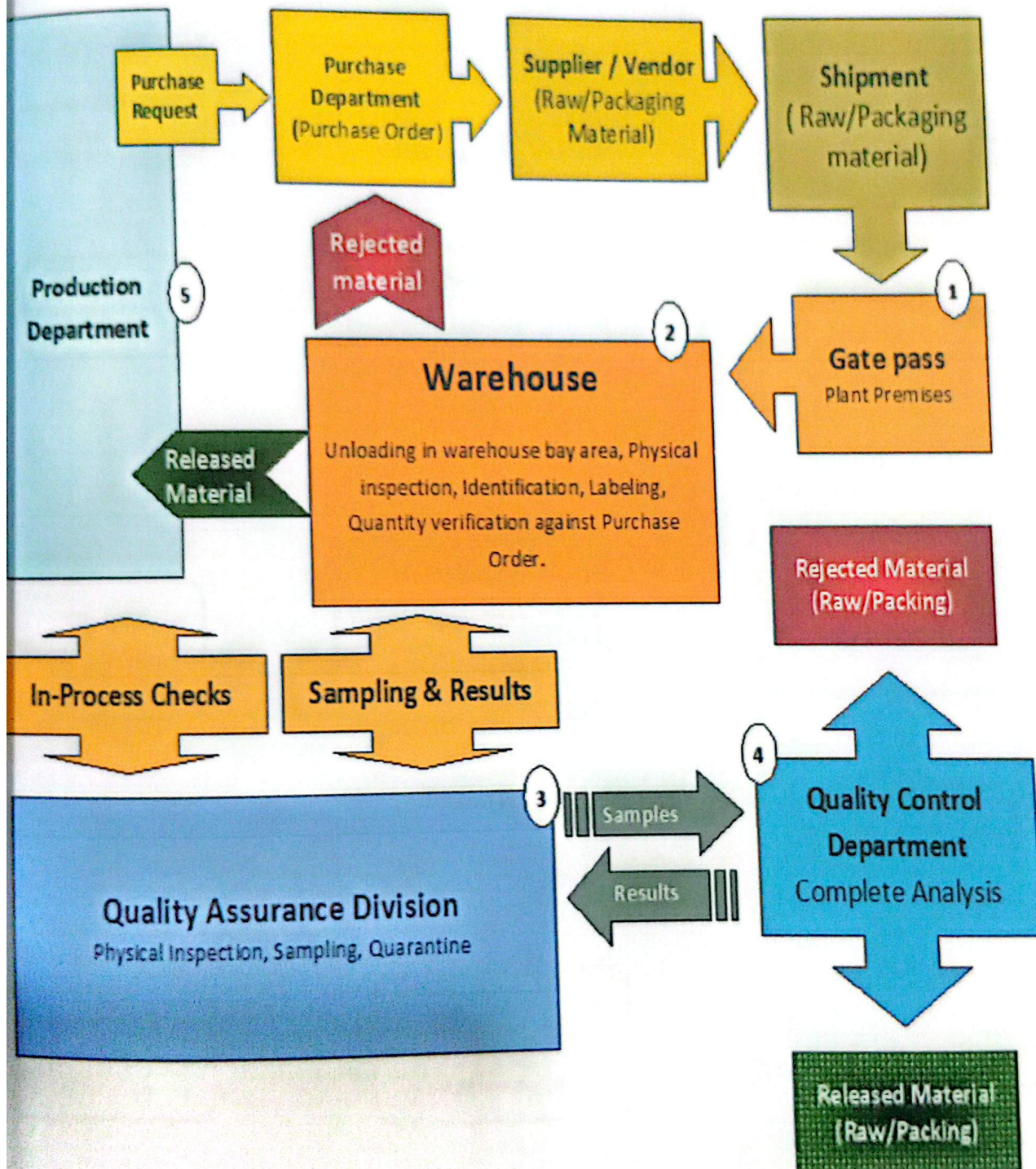


Figure 3.2: Facility General processing flow diagram

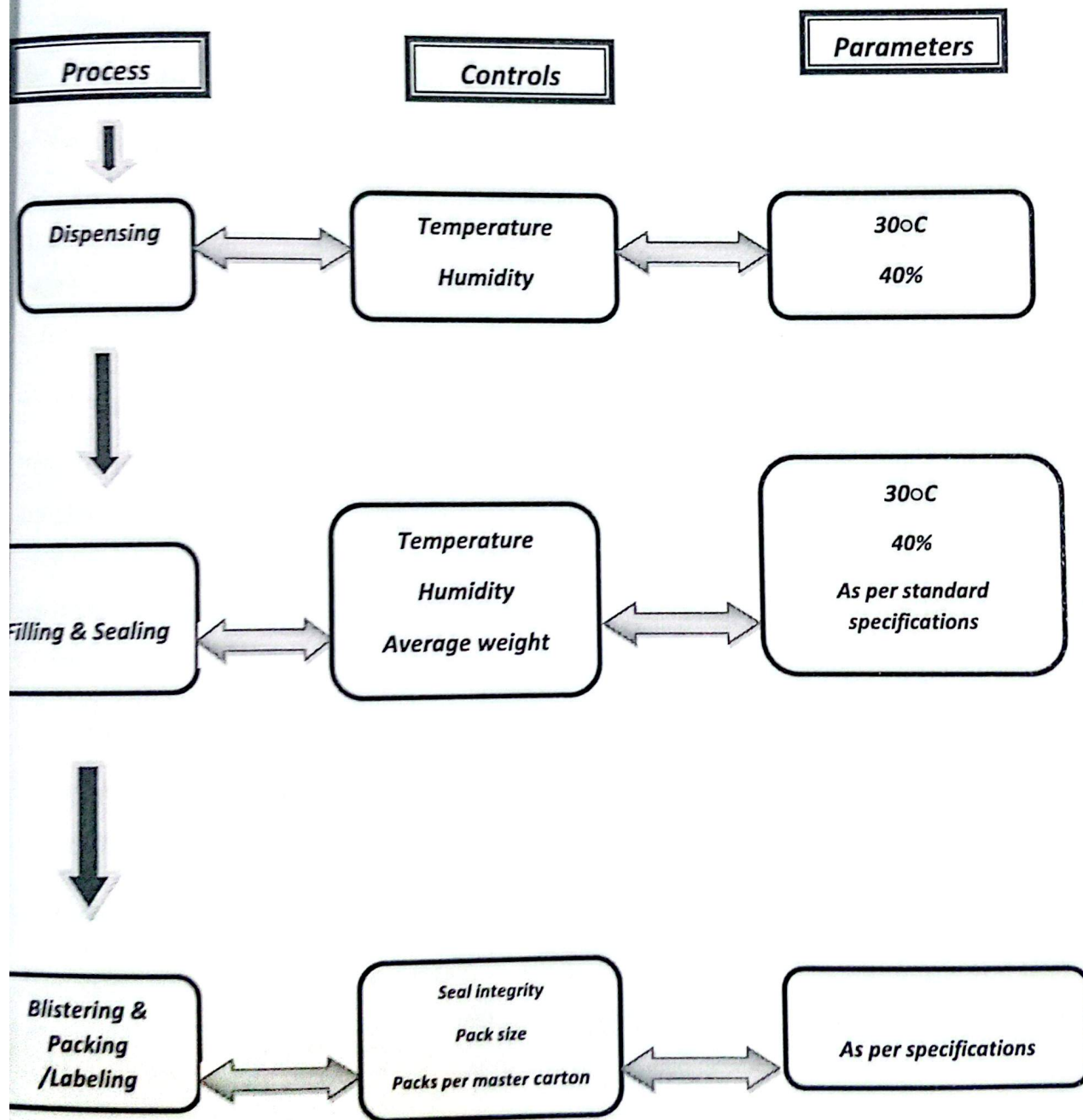


Figure 3.3: Production flow chart of Orals

Supplies

Machinery

Machinery provided in Arreta pharmaceuticals(Pvt) Ltd. is attached as annexure 6.

Manpower (Direct & Indirect)

Project requires manpower during the operational phases. During the operation phase project, the total manpower requirement is estimated to be 50-60 people (Both Direct & Indirect) comprising administrative, technical, and non-technical persons. These include pharmacists, chemists, computer operators, accountants, administrative assistances, clerks, etc. All recruited staff will be given appropriate training in order to educate them on the specific job tasks to be performed.

Firefighting, evacuation plan, Health & Safety and HVAC plan

The fire-fighting system includes water and gas devices / extinguishers. Plant has established a proper fire-fighting system. Fire hydrants are installed according to the codes and standards. A proper evacuation plan is formulated to cope with any emergency situation. Assembly points are set and marked. Fire fighting and emergency plan is attached at 7.

Electricity

EPDA will be the main supplier of electricity for this pharmaceutical unit. A diesel-fired standby generator (40 Kw) will provide electricity for this Unit in load-shedding conditions.

Water supply

The water requirement for the project includes drinking water, Process water and water for fire hydrants. Ground water (1 bore well) supply is used to fulfill this demand. Water treatment plant is provided for quality medicines (design is annexed 8).

14 Environmental concerns

I. Wastewater

Wastewater from labs, production areas will be disposed-off in Tehsil Sewerage drain after proper treatment.

Municipal wastewater coming from various municipal works of the facility will be go untreated to sewerage drain leading to Ling stream/Sawan River.

II. Air emissions

No air emission is likely to be released during operation of the project; except the dust or PM to be produced during floor cleaning and other such operations, which also will not be posing any environmental threat. Wet suppression is done to control dust emissions. Generator emissions will be controlled by providing proper enclosure, tuning and maintenance.

Third party environmental reports of ambient air quality are annexed 9.

III. Noise

All the machinery is installed and operated in a closet and machinery will not be a problem of noise in the area nearby. Further Administration of the unit will take the precautionary measures to avoid the noise emissions. There is no possibility of noise pollution.

Third party environmental reports of ambient air quality are annexed 9.

IV. Solid waste

Special waste including pharma, infectious and pharma rejections etc. will be incinerated.

Other municipal waste will be sent to landfill. Recyclables will be sell to vendors.

3.15 Area Distribution

Table 3.1: Area Distribution	
Name of Section	Area
General	
General Tablet, General Capsule, Psychotropic and General Syrup 150*80.9	12,135 ft ²
Cephalosporin 53*80.9	4,287.7 ft ²
Administration Block 27.4*80.9	2,216.6 ft ²
Servant Area 69*12.5	862.5 ft ²
Total	19,501.80 ft²
Production Area	
Tablet Section	995 sq.ft
Capsules Section (General/ General Antibiotics)	228 sq.ft
Liquid Syrup/Suspension (General/ General Antibiotics)	968 sq.ft
Tablets(Psychotropic)	1556 sq.ft
Store	2195 sq.ft
Quality Control	1196 sq.ft
Packing Hall	660 sq.ft
Cephalosporin	
Dry Powder Injection (Cephalosporin)	829.14 sq.ft
Dry Powder Suspension (Cephalosporin)	267.14 sq.ft
Capsule (Cephalosporin)	247.56 sq.ft
Packing Hall	626.09 sq.ft
Store	1190.79 sq.ft
Total (Cephalosporin)	3160.72 sq.ft

4. DESCRIPTION OF THE ENVIRONMENT

This Section of the report covers a comprehensive description of the baseline conditions of the project and its related influential area with respect to the physical, biological and social aspects. In addition to the secondary data, the field survey was carried out and the environmental baseline conditions were established based on socioeconomic interviews, impact location profiles; environmental profile questionnaires and public consultations. A social survey was carried out through consultation with various communities. Interviews were conducted from the locals near the facility area. The main intention of these interviews were to acquire feedback associated with the project as well as its impacts on their daily life on short term as well as long term basis.

4.1 Physical Environment

This part examines the physical resources such as topography, soil, climate, surface and ground water resources and quality, ambient air quality and geology of not only the Project site but also the city as a whole to assess whether the project under assessment can or does have any impacts on any of these parameters. The description of physical environment of city and the project area is present in the following sub sections.

4.1.1 Climate

Rawalpindi features a humid subtropical climate with hot and wet summers, a cooler and drier winter. Rawalpindi and its twin city Islamabad, during the year experiences an average of 91 thunderstorms, which is the highest frequency of any plain elevation city in the country. Strong windstorms are frequent in the summer during which wind gusts have been reported by Pakistan Meteorological Department to have reached 176 km/h (109 mph). In such thunder/wind storms, which results in some damage of infrastructure. The weather is highly variable due to the proximity of the city to the foothills of Himalayas.

Social structures in Rawalpindi's historic core center around neighborhoods, each known as a Mohallah. Each neighborhood is served by a nearby bazaar and mosque, which in turn serve as a place where people can gather for trade and manufacturing. Each Mohallah has narrow gullies, and the grouping of houses around short lanes and cul-de-sacs lends a sense of privacy and security to residents of each neighborhood. Major intersections in the neighborhood are each referred to as a Chowk.

The average annual rainfall is 1,254.8 mm (49.40 in), most of which falls in the summer monsoon season. However, westerly disturbances also bring quite significant rainfall in the winter. In summer, the record maximum temperature has soared to 47.7 °C (118 °F) recorded in June 1954, while it has dropped to a minimum of -3.9 °C (25 °F) several occasions, though the last of which was in January 1967.

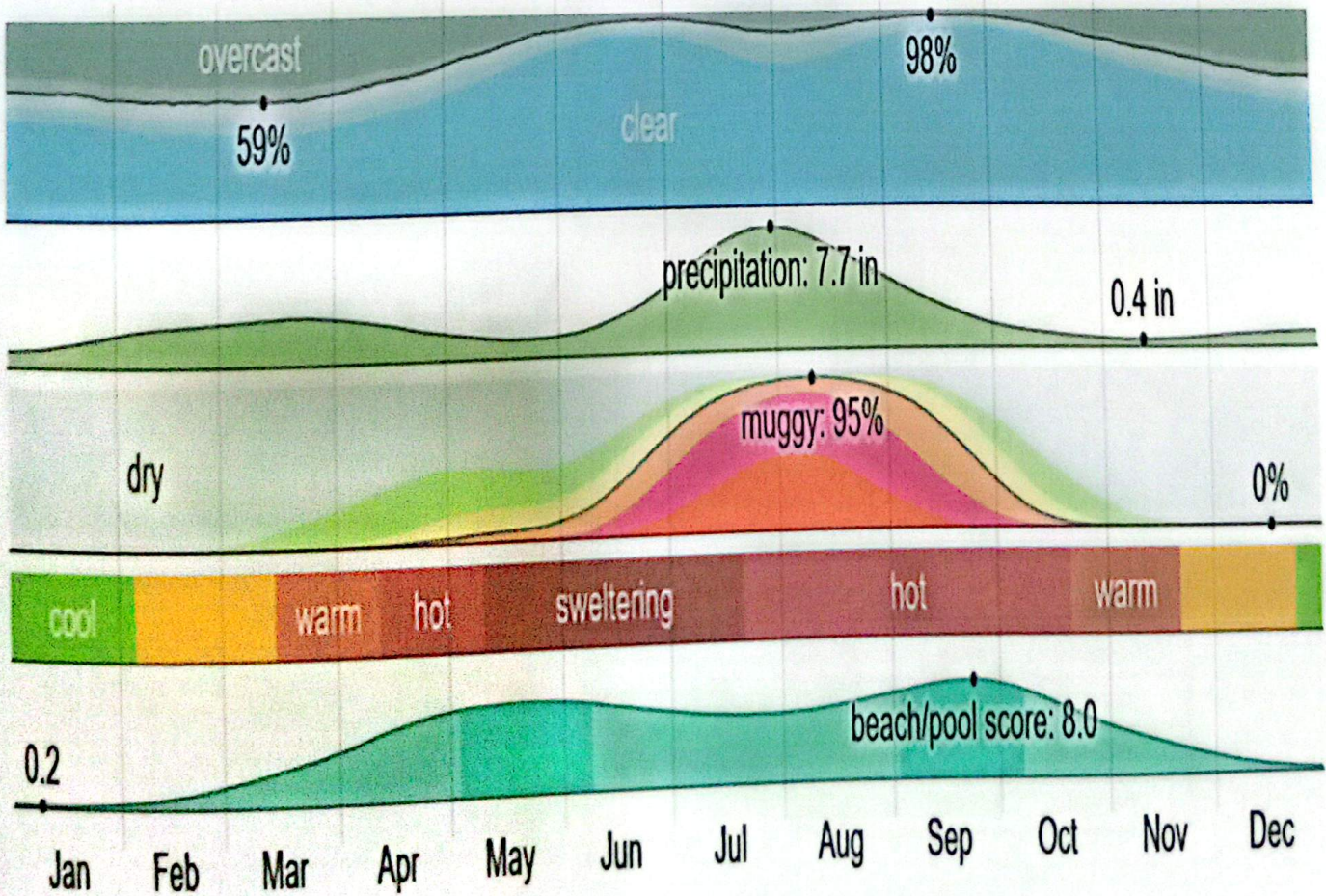
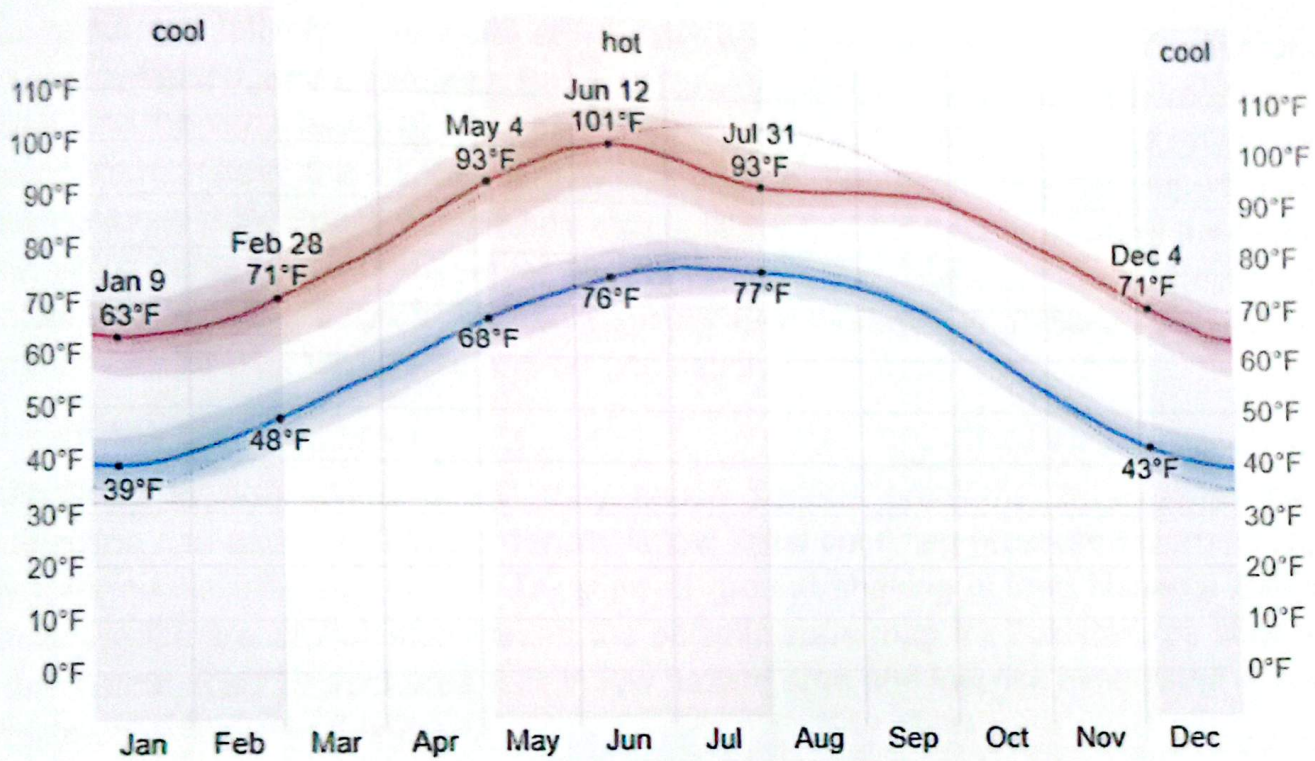


Figure 4.1: Climatic features of Rawalpindi

Rawalpindi is relatively a new city contrasted with Pakistan's millennia-old cities such as Lahore, Multan, and Peshawar. South of Rawalpindi's historic core, and across the Lahore Road, are the wide lanes of the Rawalpindi Cantonment. With tree-lined avenues and European architecture, the cantonment was the main European area developed during British colonial rule. British colonialists also built the Saddar Bazaar south of the historic core, which served as a retail center geared towards Europeans in the city. Beyond the cantonment are the large suburban housing developments that serve as bedroom communities for Islamabad's commuter population.

Seismicity

An earthquake in non-cohesive soil may cause serious problems. In extreme cases, liquefaction can occur if Relative density is low Initial confining pressure (overburden) is low earthquake intensity is high Duration of ground shaking is long National Seismic Commission of Pakistan issued the seismic zone map for Pakistan, as shown in the figure below. Said Project area falls in low hazard area and low risk associated with the structure found in this area.

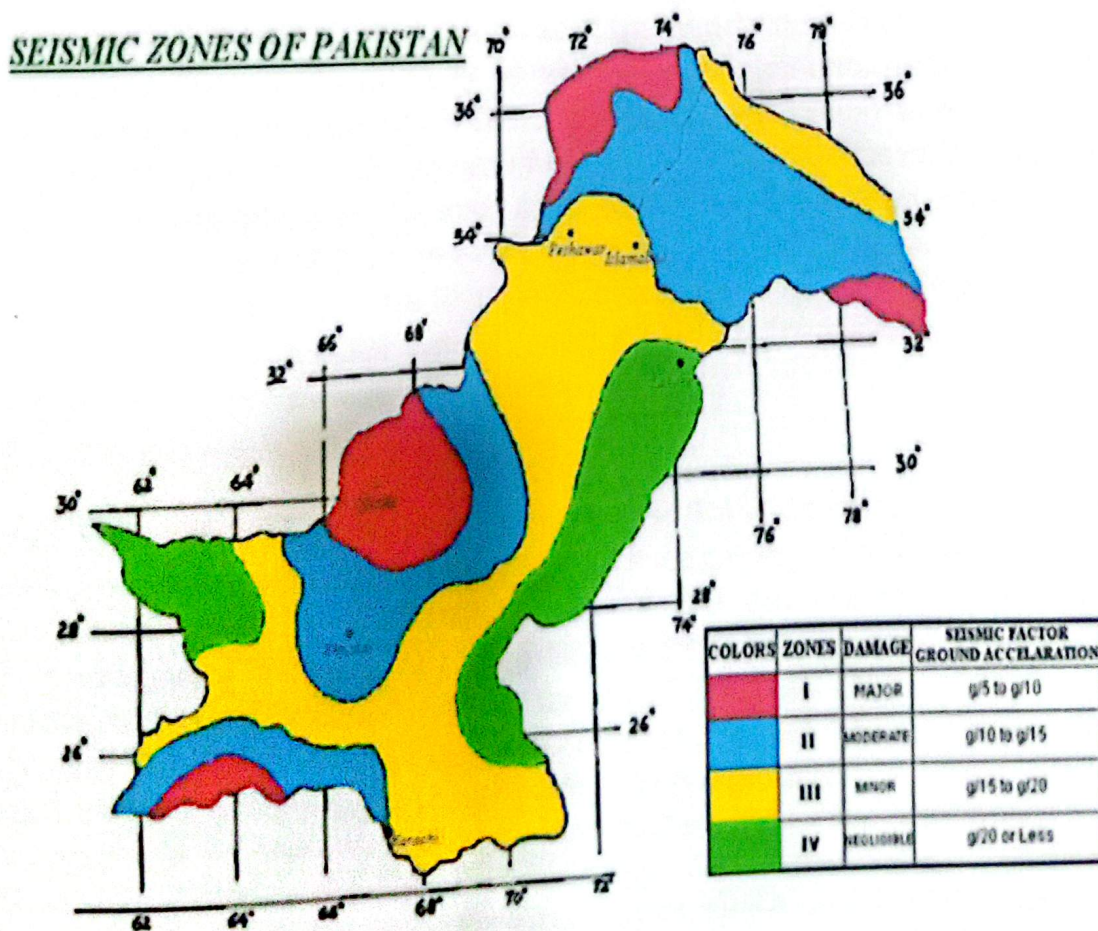


Figure 4.2: Seismic Zoning of Pakistan

ty is located in Rawat Industrial estate (Latitude:33.520776 and Longitude: 73.08518), Rawalpindi. The surrounding areas near the RCCI Industrial estate are shown in Figure 3.1. Rawalpindi Chamber of Commerce & Industry (RCCI) had been working since 1982 to establish an Industrial Estate in Potohar basically to promote industrial growth and create job opportunities for the local residents. It was in 1988 that the Government of Pakistan announced industrial incentives to encourage industrial growth in rural areas of the country. The RCCI proceeded to give impetus to the project for the establishment of an Industrial Estate in 1992 envisaging early industrial growth under the new industrial policy.

Hydrology

Soan and Kurang Rivers are the main streams draining the area. Their primary tributaries are the Ling River, draining northwestward into the Soan; Gumreh Kas, draining northwestward into the Kurang from the area between the Kurang and Soan; and Lei Nala, draining southward into the Soan from the mountain front and urban areas. The Kurang and Soan Rivers are dammed at Rawal and Sambli Lakes, respectively, to supply water to the urban area. Extensive forest reserves in the headwaters of the Kurang and Soan Rivers benefit the quality and quantity of supply. A supplemental network of municipal and private wells as deep as 200 meters (m) produces ground water primarily from tertiary alluvial gravels. The altitude of the water table decreases from about 600 m at the foot of the Margala Hills to less than 450 m near the Soan River, so that the saturated zone generally lies 2–20 m below the natural ground surface (Ashraf and Hanif, 1998). Lei Nala carries most of the liquid waste from Rawalpindi and contributes greatly to the pollution of the Soan River below their confluence. Solid-waste disposal practices threaten the quality of ground-water reserves.

Terrain

The terrain in the metropolitan area of Islamabad/Rawalpindi consists of plains and mountains whose total relief exceeds 1,175 m. Three general physiographic zones trend generally east-northeast. The northern part of the metropolitan area lies in the mountainous terrain of the Margala Hills, a part of the lower and outer Himalayas, which includes the Hazara and Kala Chitta Ranges. The Margala Hills, which reach 1,600-m altitude near Islamabad, consist of many ridges of Jurassic through Eocene limestone and shales that are complexly thrust, folded, and generally overturned. South of the Margala Hills is a southward-sloping piedmont bench underlain primarily by folded sandstones and shales of the Rawalpindi Group (Miocene). Although the relief of the piedmont area is generally low and dominated by extensive plains of windblown silt, the piedmont area also includes many ridges and valleys that have been buried by alluvial deposits from the hills. Buried ridges of sandstone are generally covered by interbedded silt and limestone gravel that locally exceed 200 m in thickness; these deposits, in

turn, have been dissected and then buried under a layer of Eolian loess and reworked silt that locally exceeds a thickness of 40 m. The gravel and loess are especially important to the environmental geology because they form most of the building foundations and because gravel is the primary ground-water aquifer. West of Rawalpindi, plains of thick, easily eroded loess are extensively dissected into shallow badland valleys. East of Rawalpindi, the folded ridges of Rawalpindi Group rocks rise above the alluvial cover to form prominent hills. Urban development is concentrated in the piedmont bench area, which is little dissected in its northern part, where Islamabad is located, but is more deeply dissected toward the south near the Soan River, where Rawalpindi is located. In the southernmost part of the area, the Soan River valley extends generally along the axis of the Soan syncline at an altitude of about 425 m. The Soan is incised more than 40 m below the level of extensive silt-covered plains north and south of the river. Southeast of Rawalpindi, upstream from the Grand Trunk Road bridge, the Soan channel and flood plain extend 1.5 kilometers (km) across the valley floor. Elsewhere, the valley bottom is much narrower. Beds of fluvial sandstone, mudstone, and conglomerate of the Siwalik Group of Neogene to Pleistocene age underlie the southern area and crop out along the many steep-sided stream valleys that dissect the land. The beds dip steeply on the north limb of the syncline north of the Soan River, and more gently on the south limb. The piedmont bench and Soan valley make up the northern edge of the Potwar Plateau), which extends southwestward for 150 km.

1.5 Geology

The dominant factor controlling the geology of the Islamabad-Rawalpindi area is the convergence of the Pakistan-India and Eurasian tectonic plates and the collision between these plates that began about 20 million years ago. This process produced complex structure and stratigraphy in the Islamabad/Rawalpindi area that have been studied by many Pakistani and foreign geologists. Most of the individual quadrangle maps comprising the study area have been mapped by the Geological Survey of Pakistan (, though many have not yet been published. This mapping has been interpreted and compiled by the first three authors of this report into a map at 1:50,000 scale (Williams and others, 1999) of the same area covered by plate G1. Plate G1 shows some of the information on the geologic map, but many geologic units of various ages have been mapped together on the basis of their physical properties, and much of the structural detail has been omitted.

1.6 Water Resources

Rawal Dam and Khanpur Dam are major water resources for the capital city Islamabad. Khanpur Dam also supplies water to Rawalpindi city along with Rawal Dam. The groundwater aquifer is recharged by surface water. The sub-soil groundwater table within the immediate subproject area is about 35-40 feet. The quality of the groundwater is such

that it is suitable for domestic use. The main source of irrigation water are the tube wells and boring system.

4.1.7 Ambient air quality

All the parameters of ambient air quality after 24 hrs. air monitoring of the facility were observed below the PEQS limits (also report is attached in annexed 9).

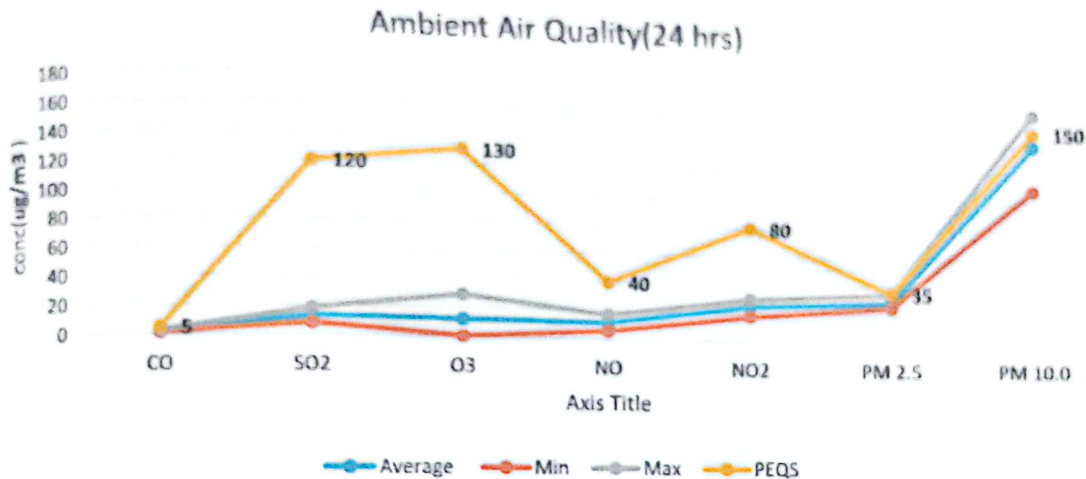


Figure 4.3: 24hrs Ambient Air Monitoring Record

4.1.8 Noise

Noise level observed at project site was within PEQs limits. Results are annexed 9.

4.2 Ecological Environment

4.2.1 Flora and Fauna

The city of Rawalpindi is located within the Himalaya hotspot and at the intersection of three different ecoregions – the Western Himalayan Subalpine Conifer Forests, the Himalayan Subtropical Pine Forests, and the Baluchistan Xeric Woodlands. All three ecoregions possess rich flora and fauna, but the diversity and endemism are relatively low in the first two. The ecoregion introduction will focus on the last one.

The Himalaya is the youngest and highest mountain chain on Earth, and stretches in an arc across multiple national borders, including that of Pakistan, Nepal, Bhutan, India, and China. The hotspot features rugged, largely inaccessible mountainous landscapes, which make surveys difficult. Significant areas of forests are still little or entirely unexplored. Thus, its biodiversity is likely underestimated. Additionally, many unique and small cultures reside in the Himalayas. The northeast part of India in particular, contains more than 500 distinct ethnic groups.

Despite its remoteness and inaccessibility, the Himalaya has not been spared from anthropogenic biodiversity loss. Greater link to the global market in recent decades has raised the demand for natural resources from the area, and steadily increasing population has led to extensive conversion of forests and grasslands. Cultivation of some crops such as barley, potato, and buckwheat reach into high elevations, and more lands are cleared in the summer months for livestock grazing. Logging (both legal and illegal) often occurs on extremely steep slopes, resulting in heavy erosion. Other threats include poaching, overexploitation for traditional medicine, poorly managed tourism, and political unrest. A reappraisal in 2004 classified the Himalayan regions into two hotspots – the Indo-Burma and the newly distinguished Himalaya. CEPF's 5 million US dollar investment from 2005 to 2010 concentrated on the Eastern Himalayas.

This ecoregion covers Rawalpindi's urban center and extends to the southeast. The Western Himalayan subalpine conifer forests represent the frontline of the forested regions in the western Himalayas, between 3,000 and 3,500 m, standing against the treeless alpine meadows to the north. Monsoons that sweep in from the Bay of Bengal contribute most of the rainfall, and thus create the east to west descending moisture gradient. Also, several birds and mammals exhibit seasonal migrations up and down the steep mountain slopes and depend on contiguous habitats for these movements. Although the region does not have a particularly rich biodiversity, it does harbor several focal large mammals of conservation importance. One of those is the Critically Endangered Himalayan brown bear (*Ursus arctos isabellinus*), a subspecies of the brown bear (*Ursus arctos*). More than 70 percent of the original habitats have been cleared or degraded in the ecoregion. Slopes have been deforested for intensive cultivation, and the collection of highly prized yellow morel mushrooms (*Morchella esculenta*) coincides with several animals' breeding seasons. In addition, collection of wood for both locals and tourists poses significant threats to the slow-regenerating forests. Currently, 9 percent of the ecoregion is protected in designations like sanctuaries and national parks, including one World Heritage site – the Great Himalayan National Park Conservation Area. The protected areas possess a 3.02 percent connectivity.

Trees commonly found in the district are Shisham, (*Dalbergiasisoo*), Keekar (*Acacia Arabica*), Shareen (*Albizialebbck*), Bari (*ZiziphusJujuba*), Guava, Citrus etc. In the recent past some farmers have started growing mini forest of Eucalyptus and Symbal etc. There are some marshy areas along the river Ravi where water stagnates. These areas are popularly known as Baila. The area is also covered with tall grass, reeds and spices. Animals like jackal, wild rabbit, foxes, wild cats, wild boar are commonly found in the entire district.

4.2.2 Endangered Flora and Fauna; Punjab Province

Punjab Urial, blue bull (nilgai), hog deer, spotted deer, Indian mole rat, Indian gerbil, field mouse, Mediterranean Pygmy shrew (the smallest known mammal), Rhesus monkeys, and the mugger crocodiles are believed to be already extinct in Punjab, while the Indus River Dolphin (the blind dolphin), Indian rhinoceros, white-backed vulture, black pond turtle, and gharyal are threatened. The Western Himalayan temperate forests of northern Punjab are under threat due to the high rate of deforestation.

4.2.3 Protected Areas and Reserved Forest

The most important protected area near the city is the IUCN-category V Margalla Hills National park (174km²) just north of the city. The park was changed from a wildlife sanctuary to a national park in 1979, and is currently threatened by poaching, logging, and urban expansion, namely hotel and resort developments. The increased popularity of the park has also caused the creation of a road, fragmenting the natural area.

In the same conservation category as Margalla Hills, Ayubia National Park (reportedly 17 km²) does not seem like effective conservation areas. Indeed, leopard in Ayubia sustained by feeding on livestock, putting farmers at risk. Aside from the category-IV Islamabad Wildlife Sanctuary (70km²), the rest of protected areas in the city are game reserves, and include the Khari Murat (56km²), Kathar (11km²), and Mori Said Aili (2.4km²) reserves. To the west of the city, protected areas are located deeper in the mountains, and the area immediately next to the city is not protected. Finally, although not a significant conservation site, the Morgah Biodiversity Park plays an important role in raising awareness among locals, and in providing plants for medicinal research.

Aside from the category-IV Islamabad Wildlife Sanctuary (70km²), the rest of protected areas in the city are game reserves, and include the Khari Murat (56km²), Kathar (11km²), and Mori Said Aili (2.4km²) reserves.

4.3 Socioeconomic Environment

This section provides collective information about the existing socio-economic and environmental condition of the project area within the AOI. The different types of socio-economic aspects were covered such as demographic profile, occupation, education and health facilities. This data helped in identifying major interventions for the development of Environmental Management and Monitoring Plan (EMMP). The study also helped to assess the positive or adverse impacts on local community.

4.3.1 Nearby industries

The industries lying in this area include poly-foils private limited(Digital printing service), Sky Pack Flexible Packaging Factory(Packaging company), Biosalus Pharma Pvt Ltd (Pharma Manufacturer), Golden (Pvt.) Ltd(Food manufacturer), WNB Minerals And Industries(Manufacturer), Grand Green Associates Pvt Ltd. playing fundamental role in the economy of the area.

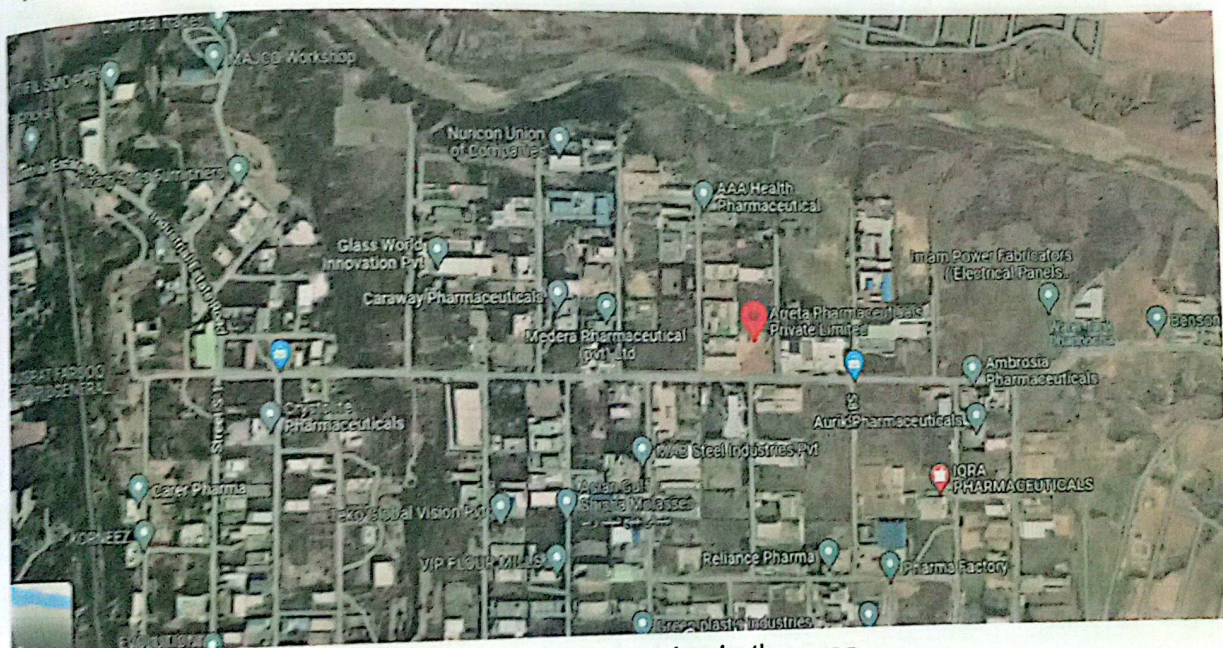


Figure 4.4: Nearby industries in the area

4.3.2 Educational facilities

Nearby educational facilities are shown in figure below.

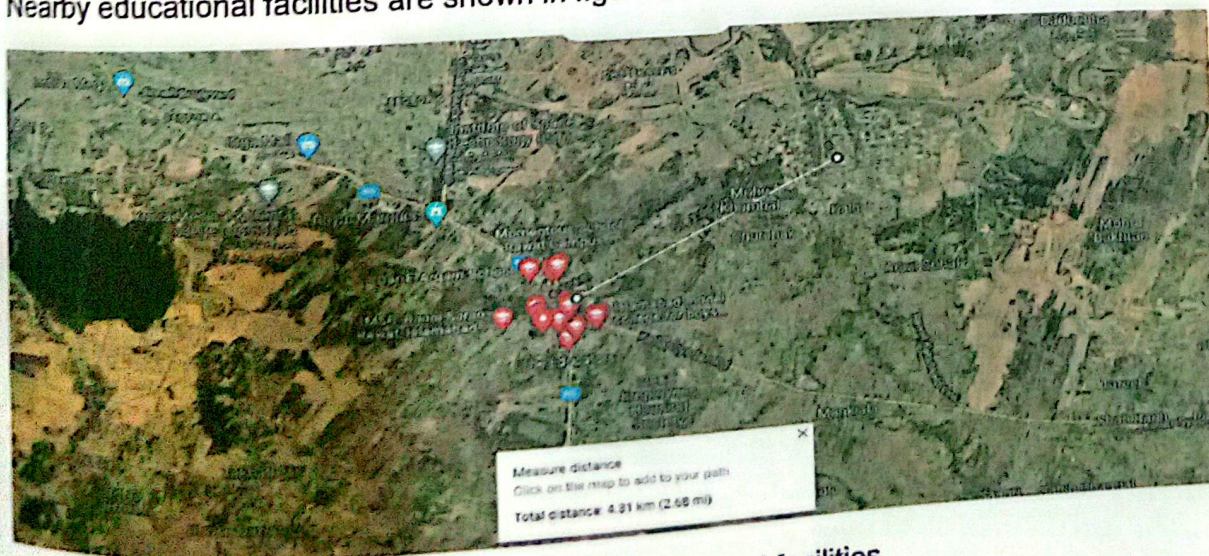


Figure 4.5: Nearby educational facilities

3.3 Religious and Archaeological Sites

There exist no documented or known sites of archaeological, historical, cultural or religious significance at or in the immediate vicinity of the proposed site.

3.4 Employment

More than 90% of the population is engaged with businesses and employments. Mostly people are either serving in Government, having own businesses, working in private jobs or are employed abroad.

3.5 Hospitals

Healthcare facilities near to project are shown in figure.

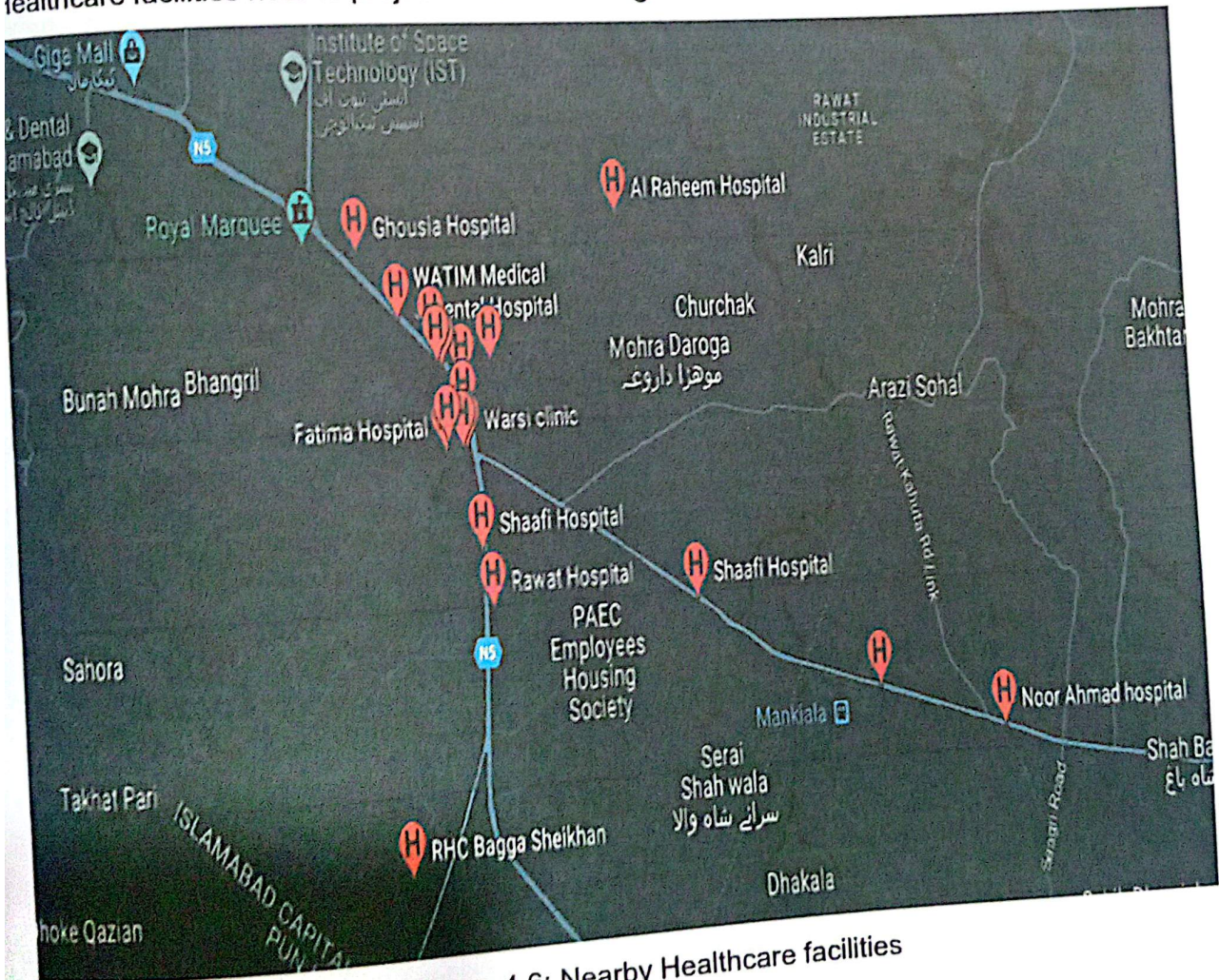


Figure 4.6: Nearby Healthcare facilities

5. STAKEHOLDER CONSULTATION

Public consultation plays a vital role in studying the effects of any development project on stakeholders and in its successful implementation and execution. It affords an opportunity to exchange knowledge with those who as members of the society are concerned with the Project, immediately or remotely. Referring particularly to a project related to environmental assessment, involvement of public is all the more essential, as it leads to better and more acceptable decision-making.

The overall objective of the consultation with the stakeholders is to help verify the environmental and social issues, besides technical ones, that have been presumed to arise and to identify those which are not known or are unique to the Project. In fact, discourse with many who have thoroughly observed the site conditions in the pre-developmental phase, goes a long way in updating the knowledge and understanding. The EIA team has made detailed survey to find such impacts but it was necessary to involve all the stakeholders at the EIA stage.

Stakeholders concerns regarding various aspects, existing environment, and impacts of the project were pointed out and added to this EIA report.

5.1 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 projects. Public involvement is a compulsory feature of environmental impact assessment, which leads to better and more acceptable decision-making. The overall objective of the consultation with stakeholders is to 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 project.

The important general objectives of the consultation process are:

- Providing key project information to the stakeholders, and to solicit their views on the project's potential or perceived impacts,
- Identification of potential problems and needs,
- To devise the way for collaborative problem solving,
- Develop and maintain communication links between the project proponents and stakeholders, providing opportunities to the public to influence the project design in a positive manner, and
- Ensure that views and concerns of the stakeholders are incorporated into the project design and implementation with the objectives of reducing or offsetting negative impacts and enhancing benefits of the proposed project.

This report includes all the comments, which were taken into account in preparing the definitive development concept for the establishment of said project. Public consultation Performa is attached as annexure 10 of this EIA Report.

5.2 Methodology

5.2.1 Identification of stakeholders

All the people who are directly or indirectly affected or concerned with the project are the stakeholder. Besides the living population of the surrounding areas, some other stakeholders were identified and contacted. They are the key players including; shops owners, vendors, public offices, schools. Not only published material (Both brief and comprehensive literature were obtained on request) but also noted their views and the concerns.

1. **Direct Potential** stakeholders(PAPs) can be;
 - Nearby residents (either property owners or the tenants),
 - Owners of the nearby industries,
 - Land owners
 - Business community around the site (Traders, shopkeepers, vendors, transporters, restaurant owners etc.)
 - Employees of the commercial entities.

As building is already constructed and property is owned, no disturbance on the local community is being foreseen due to the operation of the said plant.

2. **Indirect impact** will occur on those who are living or doing business within project area of influence.

Indirect respondents include;

- Government agencies responsible to deal with the project related activities
- Government Agencies directly, indirectly or widely involved in the execution and monitoring of the said project
- Workers of political, cultural, religious or social scientific bodies, directly or indirectly related

5.2.2 Public disclosure

It is the outcome of all such activities where public is involved at least in the information sharing process. This is an integral part of that process so before the proponent applies for NOC to the EPA, this disclosure will be distributed properly among all stakeholder. It is the responsibility of the proponent and the consultants to display public disclosure document at prominent places where community has easy access.

5.2.3 Consultation process

This process is intensified during the EIA Studies, and separate rounds of public consultations were held. Surveys were carried out in order to investigate physical, biological and socio-economic resources falling within the immediate area of influence of the project.

Primary data collection included:

- Data collection regarding the socio-economic condition of the study area
- Pretesting of socio-economic survey tools in the field
- To consult the locals for collection of information on biological environment

Various meeting with the stakeholders were held the following objectives,

- Share information with stakeholders on the said project and expected impacts on community in the vicinity of the project
- Understand stakeholders' concerns regarding various aspects of the project, including the existing condition of the upgrading requirements, and the likely impact of construction and operation activities
- Provide an opportunity to the public to influence the project design in a positive manner
- Obtain local and traditional knowledge, before decision making
- Increase public confidence about the proponent, reviewers and decision makers
- Reduce conflict through the early identification of controversial issues, and work through them to find acceptable solutions
- Dissemination of information through discussions, education and liaison
- Documentation of information narrated by the stakeholders and mitigation measures proposed by the stakeholders
- Incorporation of public concerns and their address in the EIA; and eliciting their comments and feedback.

Stakeholders consulted and their valuable suggestions and comments are described below:

5.2.4 Consultation Mechanism

The main document for distribution to stakeholders during the consultations was Social Impact Assessment Interview.

Primary stakeholders were consulted during informal and formal meetings held in the project area. The consultation process was carried out in the Urdu language. During these meetings a simple, non-technical, description of the project was given, with an overview of the project's likely human and environmental impact. This was followed by an open discussion allowing participants to voice their concerns and opinions. In addition to providing communities with information on the said project, their feedback was documented during the primary stakeholder consultation. The issues and suggestions raised were recorded in field notes for analysis, and interpretation.

By reaching out to a wider segment of the population and using various communication tools such as participatory needs assessment, community consultation meetings, focus group discussions, in-depth interviews, and participatory rural appraisal EIA involved the community in active decision-making. This process will continue even after this EIA has been submitted, as well as during future EIA in which similar tools will be used to create consensus among stakeholders on specific environmental and social issues.

Secondary stakeholder consultations were more formal as they involved government representatives and local organizations, consulted during face-to face meetings. They were briefed on the EIA process, the project design, and the potential negative and positive impact of the project on the area's environment and communities. It was important not to raise community expectations unnecessarily or unrealistically during the

stakeholder consultation meetings in order to avoid undue conflict with community's leaders or local administrators. The issues recorded in the consultation process were examined, validated, and addressed in the EIA report.

5.3 Public Consultation Outcomes

5.3.1 Primary stakeholder's consultation

Table 5.1: Primary Stakeholder Consultation / Responses

S.no	Aspect	Overall Response	Extenuation
1	Project Awareness	67% aware 33% unaware	Un-Aware people were guided about the industry.
2	Opinionated people about the project	About 93% people favored the operation of the project keeping in view its importance and also people showed pessimistic views in general but mitigation measures and solutions to their concerns were provided	Majority of people were in favor of project. They said that project will result not only in direct jobs opportunities for locals but also will enhance subsidiary business, trade, and community development. The people were of the view that industry might also elevate education standards, struggle for career enhancement besides improvement in standard and quality of living in area. People were also of the view that industry may also be instrumental in connecting the local people with major cities and will result in increase in GDP. Very few near to 6 % only shows concerns over generator emissions, noise, wastewater and health impacts. Majority of the concerns were changed in the favor of installation after communicating the participants' proper solutions and mitigation measures. Separate route to industrial area should also be constructed as the vehicles are disturbing the residential area (commerce road) connecting the GT road and industrial area.
3	No-opinionated people about the project	7% showed no concerns	-

2 Secondary Stakeholders' consultation

Table 5.2: Secondary Stakeholder Consultation /Responses

Sl. No	Name/ designation	Location/ organization	Opinions/Concerns/Issues /Suggestions
	Muhammad Rafique	EPD	There will be no harm to general public living in the vicinity of the project location as the industry is quite far away from residential area.
	Atta Muhammad (Field Inspector)	EPD	• EHS plan should be enforced strictly • Proponent should install proper wastewater treatment plant • Should work for local people benefit • Preventive measures should be adopted to avoid any unfortunate incident • Environmental enhancement measures such as; Tree plantation, monitoring and safety should be ensured
	Imtiaz Hussain Memon	PAK-EPA	It is appreciable that the Environmental Impacts of the project are being assessed before the start of the project
	Fatima Tariq	FJWU	The office of Environment sciences department Fatima Jinnah Women University, Rawalpindi Campus said that they have no objection over the operation of the industry, until or unless they follow the standard parameters of industrial environmental compliance safety measures.
	Tahir Hameed Gill	Amson Vaccines & Pharma Pvt. Ltd.	• He said that as per market response the standard and quality of the medicines manufactured by company are satisfactory • Project will lead to community development will raise living standard • He also expressed that local people should be first preference for jobs.
	Mansoor Ali	Proponent Environment Management Team	• Local employment will be ensured • Tree plantation will be done to make project environment friendly • Wastewater treatment plant has been installed • No waste will be dumped improperly
	Nazia Aslam	Environment Lawyer	To avoid violation of section 11 Wastewater Treatment Plant should be installed before final discharge.

7	Dr. Sofia Khalid	AIOU Chairperson	• Local employment should be ensured. • Proponent shall work for betterment of community
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5.4 Concerns Regarding the Project

Based on the consultations, the following major concerns/ feedback were highlighted.

- About three-fourth of the total required unskilled/ semi-skilled labor should be taken from the local population. This opportunity will help to increase the household income of local population of the project area.
- Wastewater treatment should be adopted before commencing the production activities.
- Tree plantation should be planned in and around the site.
- Poor communities nearby should be accessed and supported via giving employment opportunities and free medicines etc.
- Environmental compliance as per the law should be basic policy of the company.
- Environmental management plan should be strictly followed by the proponent.

6. ENVIRONMENTAL/SOCIAL IMPACTS

6.1 Introduction

This Chapter provides;

- screening of the potential environmental and social impacts of the proposed project to assess the significance of the potential impacts of the project on the physical, biological and social environment of the project area, and
- propose mitigation measures to minimize if not eliminating the potentially adverse impacts.

Assessment of impacts depends on the nature and magnitude of the activity being undertaken and also on the type of pollution control measures that are envisaged as a part of the project proposal.

6.2 Environmental Impacts Assessment Process/methodology

This section provides the environmental impacts assessment process that was employed during the present EIA study.

6.2.1 Potential Impacts

Under this EIA study, the potential impacts that are likely to arise during the operational phases of proposed project were identified (Table 6.1).

The impact assessment methodology defines three levels of consequences (or severity) and likelihood (chance of occurrence) i.e. Low, Moderate/Medium or High. The significance of an impact is determined on the basis of the level of consequence and likelihood of the impact.

The potential impacts thus predicted were characterized as follows:

Table 6.1 : Definitions of severity and likelihood of impacts

Level	Severity of Impact (Consequence)	Likelihood
High	- Serious / catastrophic damage to local and regional environment - Serious threat to corporate reputation/ profitability / ability to do business	- High likelihood of occurrence during lifetime of operation - Regular / continuous part of operations
Moderate	- Measurable damage to the environment - Potential to affect reputation / cost - Reduced efficiency	- Moderate possibility of occurrence during lifetime of operation - Periodic / occasional part of operations
Low	- Negligible damage to the environment - No risk to business	Unlikely to occur during lifetime of operation

impacts were characterized.

The identified potential impacts of the project are evaluated on the basis of following criteria:

1. The present baseline condition, the change in environmental parameters likely to be affected by the project related activities;
2. Is there any impact that environmental standards or environmental guidelines applicable to the project will be breached?
3. Is there a high risk of permanent, irreversible, and significant change to environmental condition due to particular project activity?
4. Did the community express any concern about this aspect?

The prediction of impacts also includes the duration of impacts in terms of short-term or long-term, nature of impact, geographical location of the impact, reversibility of the impact.

Various aspects of the impact characterization illustrated in the Table 6.2.

Table 6.2: Impact Assessment Criteria

S.no	Impact Characteristics	Categories
1	Nature of the Impact	<i>Direct:</i> The environmental parameter is directly changed by the project. <i>Indirect:</i> The environmental parameter is changed as a result of alteration in another parameter.
2	Duration of the Impact	<i>Short term:</i> Lasting only till the duration of the project <i>Medium term:</i> Lasting from a few months to a year <i>Long term:</i> Lasting for a period much greater than medium term impacts
3	Geographical Location of the impact	<i>Local:</i> Within the area of project of project i.e. operation site and access roads <i>Regional:</i> Within the boundaries of the project area <i>National:</i> Within the boundaries of the country.
4	Timing	Project phase: Before, During and After construction
5	Reversibility of the impact	<i>Reversible:</i> When a receptor resumes its pre-project condition <i>Irreversible:</i> When a receptor cannot resume its pre project condition
6	Likelihood of impact	Certain, likely, unlikely, rare

In the first step, potential impacts of the project are identified by desktop screening exercise, using checklists during field visits for collection of baseline data, professional judgment, published literature on environmental impacts of similar projects and standard environmental guidelines. Potential impacts are also identified through discussion with project proponent, consultation with stakeholder and community to identify their concerns.

6.2.3 Identification of Receptors

According to the type of potential receptors, the potential impacts are classified. The following receptor categories were used.

Table 6.3: Key Receptors

S.no	Category of Receptor	Description
1	Community	People their social and cultural values, aspirations and archaeological sensitivity
2	Land and Soil	Land resources, soil resources
3	Air Quality	Ambient air quality
4	Water Resources	Ground and surface water resources
5	Ecosystem	Vegetation, wildlife and biodiversity

6.2.4 Major impacts Aspects

The main aspects associated with potential impacts are as follows:

1. Water resources
2. Ambient Air Quality
3. Waste discharges
4. Noise pollution
5. Ecology of the area, including flora and fauna
6. Vehicle movement
7. Socio-economic conditions
8. Archaeology

6.2.5 Mitigation measures

In last, appropriate mitigation measures were recommended as part of this EIA, thus reducing the likelihood of occurrence and severity of the potentially adverse impacts.

6.3 Impacts Analysis

6.3.1 Problems

The project is about pharmaceutical industry, namely "Arreta Pharmaceuticals (Pvt.) Ltd.". The major impact associated with the operation of pharmaceutical industry includes solid waste management, wastewater management, fugitive dust emissions, noise emissions, tree plantation and occupational safety arrangements.

These all problems should be addressed on-site where they are being generated, to avoid the residual or adverse impacts. The problem will be generated during operation of the industry. So, it should be addressed on source, i.e. at site within the same timeframe. Proper mitigation measures will be provided according to the nature of the impacts/problems.

6.3.2 Options for Achieving Mitigation Measures

Following ways will be adopted to reduce the impacts of the proposed development:

6.3.2.1 Changing in Planning Design

The design of pharma industry is developed considering environmental risk and hazards. Moreover, there is no endangered and threatened species present in the project area. Any human settlement or infrastructure was not dislocated or dismantled due to the project development. Hence, there is no need to change the design of the project.

6.3.2.2 Improved Management and Monitoring Practices

The anticipated impacts will be reduced significantly by adopting better management activities, as it will be carried out for the betterment of the society. While environmental monitoring will be conducted on the regular basis to keep the sources of the air pollution, wastewater generation, noise and public nuisances in-check. Following practices that need to be adopted to reduce the impact significantly:

6.3.2.3 Compensation in Money Terms

Due to the development of the project, no tree cutting is involved, however, there is no protected or environmentally sensitive area present within 5.0 km vicinity of the project that could be impacted. Hence, no compensation in the monetary terms is required.

6.3.2.3 Replacement/Relocation/Rehabilitation

The project site is owned by the proponent and building is already constructed. So, no replacement, relocation and rehabilitation is required for the commencement of the aforesaid project.

6.4 Impacts matrix

Matrix method has been used to describe potential environmental impacts of the project as shown in Table 6.4. It is important to note that one activity may have varying impacts on different receptors i.e. different components of the environment. To avoid repetitions, this section describes various activities, which may have wide impacts on many receptors.

For example, waste generation and disposal will have impacts on land, water bodies, odor nuisance etc., therefore, the impacts of waste generation and disposal have been considered as one of the key areas of impacts. Similarly, gaseous emissions may be adverse for air quality; which on exposure may impact upon health of individuals and ecology in the surroundings.

6.5 Impacts Associated with Operation Phase

In this section, the environmental and socio-economic impacts associated with the said project operation activities are discussed. The impacts that are discussed are as follows:

Environmental Impacts

1. Air emissions
2. Noise
3. Traffic
4. Solid waste and by-products
5. Wastewater
6. Resource Consumption
7. Abnormal conditions
8. Occupational Health and Safety

Socioeconomic Impacts

1. Employment Opportunity
2. Community Development

6.5.1 Environmental Impacts

6.5.1.1 Air Emissions Potential Impacts

Air emissions from the project are relatively small. Particulate emissions are typically not significant as per the third party monitoring reports.

5.1.1.1 Sources

1. Fugitive dusts and emissions may result during raw material handling and storage which is relatively less likely to occur.
2. Other potential sources for air emissions are combustion products (nitrogen oxides, sulfur dioxide, particulate matter, carbon monoxide) from standby diesel generators and combustion products from vehicles used for project activities. The emissions from standby generators will be less in concentration. The emission levels depend on the type and quality of fuel and the manner in which it is burnt.

5.1.1.2 Mitigation measures

The proposed mitigation measures to reduce the impacts on air quality during the proposed operation activities are:

1. Clean and maintain a sufficient level of temperature and humidity in every section.
2. Proper handling of raw material to minimize the likelihood of fugitive dust and emissions during storage.
3. Monitoring of Ambient air parameters (Particulate matter, SO_x, NO_x) emissions should be carried out on regular basis to ensure compliance with the PEQS.
4. Plantation of indigenous trees within the premises and along the boundary.
5. Adequate number of plants and trees are planted along the periphery of the unit and available open spaces.

6.5.1.1.3 Residual impact

If proper mitigation measures are effectively implemented, the residual impact of the proposed activities on the area's air quality is expected to be low in terms of significance.

6.5.1.2 Noise Potential Impacts

Noise from the project operational activities are relatively insignificant as per the third party environmental monitoring reports.

6.5.1.2.1 Sources

The main sources of pollution from noise are;

1. During loading and unloading of the raw material and finished goods, vehicle movements, operation of machines. The increased noise may be a source of disturbance to workers, working near to the machines.
2. Noise level during operation phase of pharmaceutical unit will be limited to operational site. Workers could be exposed to high noise levels, however only concerned staff will be working in the area with required personal protective equipment (PPE) to minimize or reduce the noise exposure.
3. The residential area is located at a distance of more than 1.5 km away from the project site and there will be no significant impact on the community.

1.2.1 Mitigation measures

Following mitigation measures will be undertaken in order to further reduce the noise levels:

1. Effective noise suppression design and plan has been made for all noise producing equipment i.e. high noise generating machines are kept in isolated cubicles/chambers equipped with proper PPEs for machines operators to minimize the overall cumulative noise and also to keep others workers away from source.
2. It will be ensured that generators, vehicles and other potentially noisy equipment are in good condition. Noise from generators, vehicles, other equipment and machinery will be kept to the minimum through regular maintenance.
3. Noise monitoring will be carried out periodically.

1.2.2 Residual impacts

Implementation of the mitigation measures proposed above will result in negligible to no residual impact due to pharmaceutical unit noise on the surrounding environment.

1.3 Traffic Impacts

1.3.1 Source

At the operational phase of the pharmaceutical unit will result in a bit increased traffic. However, the impact will be minimal.

1.3.2 Mitigation Measures

The following mitigation measure will be implemented.

1. Vehicles will be well maintained to prevent unnecessary exhaust emissions and drivers will be appropriately trained
2. Nighttime driving of project vehicles will be limited where possible.
3. Vehicles will remain confined to defined access.
4. Speed limits will be maintained.
5. Road signage relevant to the project traffic will be placed, where necessary.
6. Community complaint register and other means will be adopted for the community to complain about non-adherence of traffic to speed limits, safe driving and other safety related concerns.
7. All vehicle drivers will be trained in community safety aspects. Drivers will be trained in responsible and safe driving practices; safe speed limits for vehicles will be followed.

1.5.1.4 Solid Waste Handling Impacts

If the waste management is not carried out properly, it can affect health of workers, pollution of soil, surface or ground water.

6.5.1.4.1 Sources

Solid waste generated from a pharmaceutical unit will comprises of;

1. Pharma waste including rejections tablets, syrups, ampules and raw pharma waste, infectious waste from labs etc.
2. Packaging waste like paper cartons, glass, metals, cardboards, plastic bags, plastic drums finished goods packaging material etc.
3. Municipal solid waste coming from kitchen, offices, cafeteria

6.5.1.4.2 Mitigation Measures

The following mitigation measures will be implemented.

1. Solid Waste Management Plan

During operational phase of the project, a proper waste management plan will be devised and implemented. Key elements of the waste management system will include the following:

- All waste generated from the project will be managed by proposed controls. Special waste including pharma, infectious and pharma rejections etc. will be incinerated. Other municipal waste will be sent to landfill. Recyclables will be sell to vendors. Most of the generated waste will be recycled. The rejected raw material will be handed back to the supplier. The generated domestic solid waste will be handled as per area practices
- *On-site handling:* Proper waste collection system will be ensured. For this purpose, waste bins will be placed inside the boundary.
- The recyclable waste will be sent to waste contractors.
- Records of generated waste should be maintained.
- All non-hazardous waste that can be recycled or reused will be handed over to the contractors.
- Training will be provided to personnel for identification, segregation and management of waste.
- All containers of waste will be labeled properly.
- In-house audits of the waste management will be undertaken on regular basis.

6.5.1.4.3 Residual impacts

Proper implementation of the mitigation measures will minimize the residual impact from waste. Monitoring and inspection will be undertaken to ensure the implementation of mitigation measures.

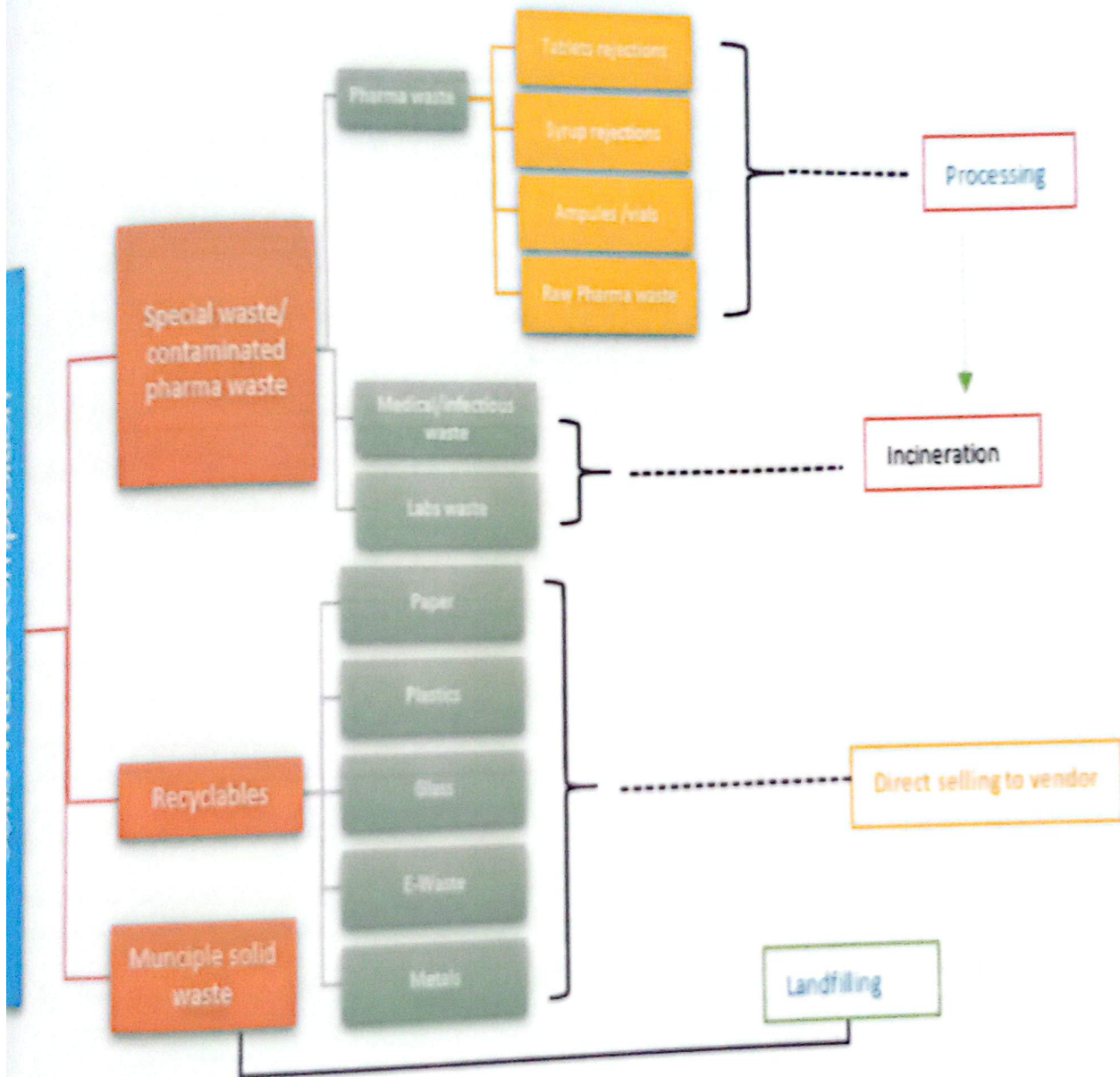


Figure 6.1: Waste Management system

6.5.1.5 Wastewater Handling Impacts

6.5.1.5.1 Source

The wastewaters generated in different processes in the manufacturing/formulation of pharmaceuticals contain a wide variety of compounds that needs treatment before final discharge from the industry.

6.5.1.5.2 Mitigation measures

- Pharma wastewater that is coming out from production areas, warehouses, labs will be disposed of in municipal drain after proper treatment. Installation of treatment plant is under process. Quotation has been received from the vendor. Effluent collection point has been constructed that cumulates all the hazardous wastewater of the unit.
- Regular monitoring of outlet wastewater will be ensured after WWTP installation.
- Municipal wastewater coming from various municipal works, such as toilets, cafeteria cleaning will not be treated.

6.5.1.5.3 Residual Impacts

Implementation of the proposed mitigation measures and regular monitoring is not likely to leave any significant impact of the waste water from the pharmaceutical unit.

6.5.1.6 Occupational Health and Safety

6.5.1.6.1 Sources

Potential occupational health and safety hazards of the operations of pharmaceutical unit can be numerous. Physical hazards may include exposure to same-level fall hazards due to slippery conditions especially during cleaning of syrup tanks. In a variety of situations, a worker can be exposed to lifting, carrying, and repetitive work and work posture injuries.

6.5.1.6.2 Mitigation Measures

In order to reduce the physical hazards and other health and safety issues that may be encountered at workplace, following measures will be taken.

1. At workplace, fire alarm system, firefighting system including different fire extinguishers, fire hydrants, fire blankets, fire balls have been installed.
2. Different PPEs have been suggested by HSE Department for different sections as per the working conditions and potential impacts.
3. Proper training will be provided for the proper usage of machineries and personal protective equipment (PPE) will be provided. It will be ensured that the individual who has received the correct training is operating a particular machine.
4. Regular housekeeping practices will be ensured by keeping the floor dry and during washing; proper protective equipment are being used. Restricted entry should be ensured during washing.
5. Training of staff in the handling of lifting materials.
6. Timely maintenance and repair of electrical equipment will be conducted.
7. Implementation of work rotations, provision of regular work breaks.
8. At workplace, first aid facilities will be maintained at readily accessible places.

6.5.1.7 Abnormal Conditions

Abnormal events might include loss of power and fire outbreak. The pharmaceutical unit will have its own backup power supply using diesel generator to protect against a loss of power. The facility will be equipped with a proper fire-fighting and emergency evacuation plan to tackle in case of any fire outbreak.

6.5.2 Socioeconomic Impacts

6.5.2.1 Potential Socio-Economic Impacts

Overall the project will have a positive impact on the employment opportunities of Pakistan.

The project is expected to have positive impact on economic condition of locals. Employment opportunities will be generated due to said project activities. The project will generate approximately 250-300 jobs during operation phase of the project. Similarly, the operation of the project will create far greater number of indirect income resources for example income resource for transporters for the transportation of the raw materials, procurement of required goods from local market etc.

A summary of potential socio-economic impacts of the project is presented in Table 6.4.

Table 6.4: Socio Economic Impacts

Impacts	Beneficial	Adverse
Economic	- Industrial growth and innovation (SDG 09) - Local manufacturing of medicines/strengthening of local economy - Role in GDP growth - Low priced medicines availability to public - Employment generation - Equipment/services procurement - Business/tax revenues - Property value enhancement	Negative impacts are not anticipated
Social	- Provision of better health (SDG 03) - Provision of livelihood opportunities to local community (SDG 1, 2) - Social security - Job provision to women (SDG 05) - Job provision to non-Muslims (SDG 10)	Occupational health and safety risks

6.5.2.2 Mitigation Measures

By implementing the following mitigation measures, projected impacts to community can be minimized.

1. Maximum number of unskilled and semi-skilled jobs will be reserved for the local communities.
2. At facility site, community complaint register will be maintained.
 - Occupational safety hazards can be minimized by adopting these mitigations.
 - At workplace, fire alarm system, firefighting system including different fire extinguishers, fire hydrants, fire blankets, fire balls have been installed.
 - Different PPEs have been suggested by HSE Department for different sections as per the working conditions and potential impacts.
 - Proper training will be provided for the proper usage of machineries and personal protective equipment (PPE) will be provided. It will be ensured that the individual who has received the correct training is operating a particular machine.
 - Regular housekeeping practices will be ensured by keeping the floor dry and during washing; proper protective equipment are being used. Restricted entry should be ensured during washing.
 - Training of staff in the handling of lifting materials.
 - Timely maintenance and repair of electrical equipment will be conducted.
 - Implementation of work rotations, provision of regular work breaks.
 - At workplace, first aid facilities will be maintained at readily accessible places.

Table 6.5: Environmental Screening Matrix (Unmitigated)

Aspects	Parameters	NATURE OF LIKELY IMPACTS								IMPACT SIGNIFICANCE				
		Low Intensity	Moderate Intensity	High Intensity	Local	Moderate Spread	Regional	Beneficial	Insignificant	Short time	Moderate	Long term		
Physical aspects	Noise													
	Air quality													
	Soil issues													
	Ground water													
	Surface water													
	Water consumption													
Biological aspects	Fauna													
	Flora													
Socio-economic aspects	Public Health and Nuisance													
	Local economy													
	Social impacts													
	Safety Hazards													
	Aesthetic Value													
	Gender Equality													
	Employment													
	Cultural issues													
	Agricultural loss													
	Compensation													

7. ENVIRONMENTAL MANAGEMENT AND MONITORING PLANS

This Chapter presents the implementation mechanism for the environmental and social mitigation measures identified during the present EIA study. The EMMP reflects the commitment of the proponent (Arreta Pharmaceuticals Pvt Ltd) to safeguard the environment as well as the surrounding population during the operations of the facility.

7.1 Purpose and Objectives of EMMP

This EMMP provides the delivery mechanism to address the adverse environmental as well as social impacts of the proposed project during its execution, to enhance project benefits, and to introduce standards of good practice to be adopted for all project works.

The primary objectives of the EMMP are to:

- To facilitate the implementation of the earlier identified mitigation measures,
- To develop a proper monitoring mechanism and identify requisite monitoring parameters to confirm effectiveness of the proposed mitigation measures,
- To ensure the complete implementation of all mitigation measures and ensure the effectiveness of the mitigation measures.
- To define the responsibilities of the project proponent (Arreta Pharma Pvt Ltd.), and provide a means of effectively communicating environmental issues among them,
- To provide a mechanism for taking timely action in the face of unanticipated environmental or social situations, and;
- Identify environmental as well as social training requirements at various levels.

7.2 Management Approach

7.2.1 Proponent

The overall responsibility for compliance with the environmental management plan rests with the project proponents i.e. Arreta Pharmaceuticals Pvt. Ltd. The project proponent will undertake overall responsibility for compliance with the EMP. Concerned Departments will carry out verification checks to ensure that the proponent is effectively implementing their environmental and social requirements.

7.2.2 HSE department:

HSE department is functional in the facility with responsible and qualified team of 4 members. The strength can be increased in future as required.

7.3 Environment Management Plan (Project Specific)

It lists all the mitigation measures identified in the EIA and the associated environmental or social aspect in line during operational phase with the administrative framework

olving all the responsible implementing authorities who are required to take the defined actions/measures. It enhances project benefits by reducing its impacts and making it environmental friendly.

1 Components of the EMMP

During the operation phase of the project, environmental and socioeconomic management will become a routine function, as an integral part of the O&M activities. The EHS department will be the focal point for all matters relating to environmental and socioeconomic issues during the routine operations of the Organization. The EHS unit will advise various departments within Arreta Pharmaceuticals Pvt Ltd. for environmental and socioeconomic issues. The EHS unit will develop an environmental and socioeconomic management system for the company, defining roles and responsibilities of various departments and their respective staff.

EMMP consists of the following

1. Management plan
2. Monitoring Plan
3. Communication and documentation
4. Institutional capacity
5. Environmental training

1.1 Management Plan

Figure 7.1 is deliberating Environmental Management Plan and the Proposed Mitigation Measures.

(Operational phase)

Objective	Management action	Responsibility	Timeframe	Residual Impacts
1. Wastewater Management				
Degradation of surface waters quality due to process water and sewage direct disposal	• Special Wastewater coming from production, labs etc. will be disposed-off in the Municipal Drain after proper treatment process for which treatment plant in planning stage. • General municipal wastewater coming from various municipal works of kitchen, cleaning, washrooms etc. will go directly to sewerage line. • Process flow diagram of WWTP is attached as annexure 11.	Arreta Pharmaceuticals Pvt Ltd.	Through-out the project life cycle	None
2. Air quality Management				
Particulate emissions and generator stack emissions	• No air emissions are likely to be released during operation of the project; except the dust or PM to be produced during floor cleaning and tablet powder coating and other such operations, which also will not be posing any environmental threat (will not breach the safe standards). • Wet suppression is done to control dust emissions. • Generator emissions will be controlled by providing proper enclosure, tuning and maintenance.	Arreta Pharmaceuticals Pvt Ltd.	Through-out the project life cycle	Local air quality will be virtually unaffected and will be based on PEQs

3. Noise & Vibration

- All the machinery is installed and will be operated in a closed hall/Cabins
- From operations of the machinery, noise will not be a problem for the workers around, nor for the nearby population.
- Further Administration of the unit will take the precautionary measures to avoid the noise emissions.
- A thick greenbelt will be developed at best possible available spaces all around the plant.
- Introduction of control and monitoring rooms having good sound insulation properties.
- All the workers will be provided with ear plugs.
- Engineering department will also keep the regular maintenance of the machines.
- All the transporters will be advised to carry out regular maintenance of their vehicles.
- Third party monitoring of noise pollution will also be carried out at monthly or quarterly basis as per the compliance policy of EDP.

To minimize disturbance of communities due to noise

Throughout the project life cycle

Arreta Pharmaceuticals Pvt Ltd.

Noise level will be based on PEQs

4. Traffic & Transport

Increased heavy vehicles traffic both locally and nationally	Restricting delivery hours to reduce noise nuisance; avoid heavy truck movements in the night hours will be considered whether deliveries should be scheduled to avoid peak times to reduce congestion.	Arreta Pharmaceuticals Pvt Ltd.	Throughout the project life cycle	The traffic has the potential to contribute to congestion and lead to complaints as heavy traffic is currently chamber road (crossing over within the residential area) using due to noise/vibration nuisance on a local basis.
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5. Occupational Health & Safety

To minimize loss work injury/hazard/incidents/accidents	- EHS department will ensure overall occupational health and safety protocols. - Regular trainings regarding EHS will be given on the regular basis. - Workers will be facilitated with PPEs such as: helmets, mask, earplugs/muffs, safety boots, etc. - It would be strictly enforced to wear PPEs while working - Workers will be trained on the regular basis regarding personal safety and disaster management - Incidents should be reported directly to the concerned authority.	EHS section/Manager Arreta Pharmaceuticals Pvt Ltd.	Throughout the project life cycle	None
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First aid Facilitation	- First aid box will be available at all the sections - First aid training will be provided to all the workers on regular basis	EHS section/Manager Arreta Pharmaceuticals Pvt Ltd.	Throughout the project life cycle	None
To prevent any fire hazards	- Firefighting equipment including DCP type fire extinguisher, CO₂ Type extinguisher, sand buckets, sand drums with spade and hose pipe cabinet have been/will be installed inside the plant - All the equipment will be placed at strategic locations where the risk of out-burst of the fire is high. List of fire posts is annexed 7. - Smoking will not be permitted in the vicinity of the plant. - Regular site inspection will be done to eliminate all the chances of the hazards - Checking and maintenance of the fire-fighting equipment will be carried out on the regular basis. - Emergency evacuation plan is annexed 7.			

7.3.1.1 Monitoring Plan

The EIA predicts the impacts of the proposed project on the basis of information available at the time of conducting the assessment and the natural processes that link various environmental and social parameters. Based on this prediction, mitigation measures are introduced such that the predicted residual effects do not exceed acceptable levels. However, there is always an element of uncertainty in such predictions due to an insufficient grasp of the processes, limitations in prediction techniques, or inadequate data on the environment. This is true for the physical, biological, as well as socioeconomic environment. Consequently, it is possible that even if the mitigation measures are implemented fully, the negative impacts of the project may exceed acceptable limits.

In order to address the above concerns, effects monitoring will be undertaken during the project activities, with the overall objective of proper management of environmental and social risks and uncertainties. Broadly, effects monitoring has the following objectives:

- To verify that the impacts of the proposed project are within acceptable limits, thus establishing credibility (public assurance)
- To immediately warn the project proponents (and the regulatory agencies, if required) of unanticipated adverse impact or sudden changes in impact trends so that corrective actions can be undertaken, which may include modifications in the proposed activities, or the inclusion of modified or additional mitigation measures
- To provide information to plan and control the timing, location, and level of certain project activities so that the effects are minimized.
- To facilitate research and development by documenting the effects of the proposed project that can be used to validate impact-prediction techniques and provide a basis for more accurate predictions of future projects.

The monitoring will be done during operational phase comprising of the following parameters:

Table 7.2: Environmental Monitoring Plan

Components	Project Stage	Sources	Compliance Standards	Sampling points	Monitoring regime	Request Initiated by	Monitoring performed by
Air	Operation	Stack emissions	PEQs	All stacks sources	Quarterly	Manager HSE (Arreta Pharma Pvt.Ltd)	Through approved third party/monitoring lab
		Ambient air quality	PEQs	Production areas	Quarterly	Manager HSE (Arreta Pharma Pvt.Ltd)	Through approved third party/monitoring lab
		Indoor air quality	PEQs	Indoor areas	Quarterly	Manager HSE (Arreta Pharma Pvt.Ltd)	Through approved third party/monitoring lab
Waste-water	Operation	Effluent Treatment plant	PEQs	Inlet and Outlet of ETP	Quarterly	Manager HSE (Arreta Pharma Pvt.Ltd)	Through approved third party/monitoring lab
Noise	Operation	Indoor noise level	PEQs	Production areas	Quarterly	Manager HSE (Arreta Pharma Pvt.Ltd)	Through approved third party/monitoring lab
		Outdoor noise level	PEQs	Factory premises	Quarterly	Manager HSE (Arreta Pharma Pvt.Ltd)	Through approved third party/monitoring lab

7.3.1.2 Roles & Responsibilities

The Proponent will utilize the following arrangements in the implementation of the EMMP during planning and operation phase. The Proponent is accountable for ensuring that resources are made available to effectively implement the EMMP and necessary environmental management measures arising from the project.

Position	Responsibility
HSE Manager	1. Operational Management & Control 2. Supervising operational activities 3. Effective implementation of the EMMP 4. Regular performance reviews 5. Corrective and/or remedial action where this may be required
HSE Officer	1. Preparation of environmental monitoring, reporting and any permit applications (if any) 2. Overseeing of operational process and ensuring the implementation of avoidance and mitigation measures 3. Conducting monitoring and review of EMMP implementation by contractor

7.3.1.3 Reporting & reviewing procedures

An effective mechanism to store and communicate environmental information during the project is an essential requirement of an EMP.

7.3.1.4 Trainings

Environmental training will help to ensure that the requirements of the EIA and EMP are clearly understood and followed by all project personnel in the course of the project. Contents related to trainings would include mitigation measures, environmental management plan, OHS etc.

7.3.1.5 Equipment Maintenance Details

Equipment/Machines will be maintained on the regular basis. The fire-fighting equipment that would be installed in the halls/buildings will also be checked and maintained on regular basis. Only fire safety equipment such as; portable fire extinguishers will be installed which will need regular maintenance and check in order to eliminate hazards of associated fire risks. Table 7.3 is the maintenance schedule for the machines and equipment.

7.3.1.6 Environmental Budget

Approximately PKR 2 Million/yr budget will be reserved for tree plantation, solid waste management, wastewater management and environmental monitoring. Monitoring tests for ambient air quality, noise and groundwater quality will also be conducted.

Table 7.3 : Maintenance Schedule

Tasks	Weekly	Monthly	Quarterly	Bi-annually	Annually
Visual Inspection	√				
Testing and Inspection				√	
Maintenance of Machines		√			
Fire Mains and Nozzles		√			
Containers/Cylinders				√	
Control and Section				√	
Valves					

7.3.1.7 Public Disclosure

Proponent will disclose this EIA and EMMP to all the stakeholders, at the commencement of the proposed project. The EIA report will be made available to the stakeholders at the sites designated by the EPA, in accordance with the PEPA 1997, section 12 (3), (i).

8. CONCLUSION AND RECOMMENDATIONS

8.1 Conclusions

The report presents Environmental Impact Assessment (EIA) of the Arreta Pharmaceuticals Pvt. Ltd.

EIA of Said Project is performed according to guidelines of EPA. It includes description of the project, description of the environmental baselines, potential environmental impacts and suggested mitigation measures. An implementation mechanism for mitigation measures in the form of an Environmental Management Plan is included in the study.

The performed EIA showed all anticipated impacts (both positive and negative), associated with the project. Appropriate mitigation measures as explained in the environmental study will strengthened the environment and promote sustainable development.

Based on overall assessment of the environmental impact of the project, it is concluded that the economic benefit from the project is not at the cost of environment. From the historical records and vast experience in sustainable development keeping environment as integral part of manufacturing system, Areeta (Pvt.) Ltd. is worthy of Environmental approval. Further the project is not likely to cause any significant adverse impact on the physical and biological environment but positive impact on social development and economic prosperity of the area, provided that suitable mitigation measures as identified in this study are implemented.

It is accordingly recommended that Environmental Approval for the project may be issued by the Punjab Environmental Protection Agency, subject to payment of the requisite scrutiny fee by the proponent of the project.

8.2 Recommendations

On the basis of the overall impact assessment, more specifically, nature and magnitude of the residual environmental impacts identified during present EIA, it is concluded Areeta Pharma Pvt Ltd is likely to cause no adverse environmental impacts during its operations. However, these some reported minute impacts can be mitigated provided the proposed activities are carried out as mentioned in the report, and the mitigation measures included in this report are completely and effectively implemented.

The project will directly improve healthcare products manufacturing and economy in Pakistan and employment opportunities for the local communities.

There are no remaining issues that warrant further investigation. This EIA is considered as adequate for the environmental and social justification of the project.

ANNEXURES

Annexure 1	Arreta Certifications
Annexure 2	Raw Materials Details
Annexure 3	List of Registered Products
Annexure 4	Site Approved Map
Annexure 5	Quality policy
Annexure 6	Machinery/Equipment Details
Annexure 7	Fire Frightening and Emergency Plan
Annexure 8	Water Treatment Plant (RO)
Annexure 9	Environmental Monitoring Reports
Annexure 10	Public Consultation Performa
Annexure 11	Process Flow Diagram of WWTP
Annexure 12	Pictorial Gallery

ANNEXURE 1

'Arreta Certifications'



B007660

SECURITIES AND EXCHANGE COMMISSION OF PAKISTAN
CERTIFICATE OF INCORPORATION ON CHANGE OF NAME

[Under section 13 of the Companies Act, 2017 (XIX of 2017)]

Corporate Universal Identification No. 0095058

I hereby certify that pursuant to the provisions of section 12 or section 13 of the Companies Act, 2017 (XIX of 2017) the name of **TAYYAB LABORATORIES (PRIVATE) LIMITED** has been changed to **ARRETA PHARMACEUTICALS (PRIVATE) LIMITED** and that the said company has been duly incorporated as a company limited by shares under the provisions of the Company Law.

This change is subject to the condition that for a period of ninety days from the date of issue of this certificate, the company shall continue to mention its former name along with its new name on the outside of every office or place in which its business is carried on and in every document or notice referred to in section 22 of the Act.

Given under my hand at Islamabad this 23rd day of May two thousand and Eighteen.

(Shahzad Afzal Khan)
Additional Registrar of Companies
Islamabad



No. ADI 37488

Dated 24/5/18

Fee Rs. 2,500/-

Book No B 13107

Serial No B 1310655

MEMBERSHIP CERTIFICATE

THE RAWALPINDI CHAMBER OF COMMERCE & INDUSTRY

Name & address of Chamber
Association

39, Civil Lines, Mayo Road, Rawalpindi

(Affiliated with the Federation of Pakistan Chambers of Commerce & Industry)

CERTIFIED that

Arreeta Pharmaceuticals (Private) limited.

Plot # 13, Street N-5, RCCI Industrial Estate, Rawat, Rawalpindi

G.S.T. No. 3277876138333

N.T.N. No. 7339369

is a member of this Chamber
Association

Since 08-July-2017

Bearing Membership #CM-1017

THIS CERTIFICATE shall be valid upto the 31-03-2023 unless
otherwise notified to the NTN / GST Registration authority / Scheduled Bank
concerned.



Given on this 28th day of Nov 22

Signature of Secretary

Counter signed by

Saqib Rafiq
President

Allotment Conditions

1. Payment including surcharge for the late remission of installment - does if any will be made prior to transfer possession transfer deed.
2. Allottee will abide by all Rules - Regulations and By-Laws of RCCI Industrial Estate Rawat.
3. Construction will be carried out in accordance with the Building Plan Approved by Crescent Developers (pvt) Ltd (CDPL) as per RCCI Industrial Estate Building Bye-Laws
4. Allotted plot will be used for bonafide Industrial - Commercial - Warehouse purposes only (as allotted)
5. The Allottee shall not disturb - interfere with the layout of the Industrial Area in any manner whatsoever and shall not encroach upon or put in to his use, the pavements, pathways, roads, beams, green belts or any of the area / Piece of land in the ownership of the CDPL, other than the one allotted to him.
6. The size and location measurement of the plot is tentative and subject to adjustment change until physical possession with demarcation certificate is taken by allottee.
7. After taking over the possession of Plot, commencement of Construction work is mandatory within one month.
8. In case the allottee wants to secure a loan from a registered financial institution (FI), he has to obtain No Objection Certificate from the management of CDPL before mortgaging the Industrial Unit / plot with request of FI.
9. Allottee will pay all dues including services charges, maintenance charges, security charges, Govt dues, utilities charges from development authority's etc as demanded from time to time by management Board, RCCI Industrial Estate Rawat.
10. Implementation of industrial project within a reasonable period of time.
11. Charges on account of transfer of allotment / Registry will be borne by the allottee.
12. Any Taxes levied by the Federal / Punjab Government should be paid by the allottee before the transfer / possession of the plot.
13. The allottee undertakes to abide by the terms and conditions given above, any other govt rules applicable and shall not dispute these terms and conditions at any forum / court / authority.



RCCI INDUSTRIAL ESTATE RAWAT

ALLOTMENT CERTIFICATE

Serial No. **5196**

Certified that

RIE-5905

M/s. Arreta Pharmaceuticals (Pvt.) Ltd.

H # 25, Nishtar Abad, Peshawar.

**Is here by Allotted Plot # 13, St. # N-5 Measuring 2400 sq yds
Type Industrial**

(Allotment conditions overleaf)

(RIZWAN EJAZ)

Director

Crescent Developers (Pvt.) Ltd.

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

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

Email: renaissancedev@yahoo.com, <http://www.renaissancedev.org>

Dated 25 November, 2022

ARRETA PHARMACEUTICALS (PVT.) LTD.			
EMERGENCY PREPAREDNESS & RESPONSE MANUAL	Document No.	Effective From	Revision No.
	AP/EPRM/001	14-02-2023	00
Quality Assurance	Reviewed By: Assist. Manager Quality Assurance	Approved By: Quality Assurance Manager	

EMERGENCY PREPAREDNESS & RESPONSE MANUAL

ADDRESS:

Plot No. 13, Street No. N-5, RCCI, Rawat, Rawalpindi, Pakistan.
Tel: (+92-51) 4499437
E-mail: arretapharma@gmail.com

ARRETA PHARMACEUTICALS (PVT.) LTD.

EMERGENCY PREPAREDNESS & RESPONSE MANUAL

Document No.

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14-02-2023

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Description

Introduction

Objective

Scope

Distribution List

1.00 Duties and Responsibilities

Identification of Personnel

Warning

Evacuation Procedure

Main Controller

Incident Controller

Area Supervisor

Fire Squad Leader

Communication Officer

Manager (Engineering)

Manager (Human Resource)

Security Officer

2.00 Emergencies

Emergency due to spillage of Liquids / Solids

Emergency due to Gas Vapors

Emergency due to Heavy Rain or Dust Storm

Emergency due to Bomb Threats

Emergency due to Major Fires

Other General Emergencies

3.00 List of Appendices

List of Important Telephone Numbers for external assistance

List of Important PABX Telephone Numbers for internal assistance

List of Important Telephone Numbers of Officers Residence

List of direct telephone lines installed in Plant

List of Hazardous Material

List of Fire Fighting / Safety Equipment available

List of Material Safety Data Sheet

Site Plan / Drain Layout

Site Plan / Gas line Layout

Site Plan / Power Supply Layout

Site Plan / Hydrant Layout

Site Plan / Water Mains Layout

Site Plan / Plant Alarm System

Fire Evacuation Zones and Assembly Points

Emergency Log Sheet

List of Hazardous Material stored in various areas.

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EMERGENCY RESPONSE MANUAL

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Effective From

Revision No.

DATE PREPARED:

14.07.2023

01

The purpose of this manual is to define an emergency as a sudden event resulting in harm to human resources, equipment and/or material damage of large magnitude. Immediate action is required to prevent or limit such harm as the manual outlines the emergency circumstances and control system established in the Organization, while defining the responsibilities of the personnel concerned.

In case of an emergency, a "Disaster" which should be avoided by following the Standard operating procedure of handling of hazardous materials, correction of other dangerous material, solvent, equipment and disposing of the materials, measures at all times. However, in the Organization, where hazardous solvents, toxic gases, acids, alkalis and other corrosive materials are handled regularly by a very large number of workers, possibly a malfunctioning instrument and any negligence can prove disastrous both to human as well as equipment.

Emergency situations could be:

1. Spillage of a liquid

2. Spillage of large quantity of liquid, which

3. Spillage of low but toxic liquids

4. Spillage of toxic gases

5. Fire

6. Other incident involving, at least a large part of the facility and its workers.

1.1

Objectives of the Emergency Response Manual is to set a clear standard and control measures to counter the emergencies that can arise in the Plant.

1.2

Emergency Manual is divided into three sections:

1.1.1. Definition of Incident and Responsibilities

1.1.2. To cover emergencies resulting from major solvent spillage, spillage of acids, gas leakage, fire, etc. and low level, toxic liquid, at large scale.

1.1.3. List of Responsibilities

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Revision List

Revision on: Controlled Distribution List

Revision List

Rev No.	Designation	Issued To
001 # 01	Master Document	O&PC
001 # 02	Electronic Document	

On revision of the Manual is issued, the obsolete version should be returned to O&PC for disposal.

ARRETA PHARMACEUTICALS (PVT.) LTD.

EMERGENCY PREPAREDNESS & RESPONSE MANUAL

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Responsibilities of Personnel

Main Controller

Manager (HSE)

Incident Controller (During Normal Shift)

Concerned Department Manager

Incident Controller (After Normal Shift)

Security Officer

Area Supervisor

Department/Section Head

Fire Squad Leader

Officer (HSE)

Communication In-charge

Receptionist

Services Support Officer

Manager (Engineering)

Warning

Personnel coming across an emergency should immediately activate the Plant Alarm System and / or inform the officers by the fastest possible means mentioned in appendix 3.02

Evacuation Procedure

The employee working in the affected zone after hearing the Plant Alarm System should immediately leave their place of duty and assemble at the assembly point identified for that zone and await further instructions from the Area Supervisor.

The Area Supervisor will take a roll call to ensure that all person have come out of the danger zone.

Main Controller

On receiving first information regarding the emergency, the Manager (HSE) will proceed to the Emergency Control Center to assume overall control of the situation and have the Plant Alarm System activated if it has not already been done.

The Main Controller will broadcast the nature and location (by Zone) of the emergency on the Public Address System or Loud Speaker.

He will organize, with the help of Manager (Engineering) the isolation and disconnection of utility supplies such as power, gas, steam to the affected area, removal of equipment and materials, if required, and other salvaging operations.

He will maintain a log of the emergency as per Appendix 3.15

Organize disbursement after the emergency is over.

Incident Controller

The Incident Controller will:

- In the absence of the Main Controller, assumes that responsibility until the Main Controller's arrival.
- Assess the scale of emergency at the site, report to the Main Controller at the Emergency Control Point and intimate whether evacuation of the area is required. During off duty hours, the Incident Controller will telephone the Main Controller at home or Mobil to intimate him of the emergency.
- Receive the attendance sheet from the Emergency Control Point in case evacuation is decided upon and arranges necessary evacuation of personnel in collaboration with the Area Supervisor.
- Keep the Main Controller informed of the situation at site
- Coordinate with any outside agencies called into operation at site by the Main Controller
- Submit a final report to the Main Controller after the emergency is over.

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He will act as Incident Controller until his arrival, upon which he will intimate the Incident Controller of the situation.

He will immediately inform the Main Controller or Incident Controller of an emergency arising in his section.

He will assist the Incident Controller in the evacuation / relief operations.

He must maintain the following updated records at all times:

- List of his Staff trained in Fire Fighting procedure.

- Location of Hazardous materials in his section.

- List of evacuation zones in his section and their designated assembly points

- Location of isolation switches / valves

- List of Fire Fighting and First Aid Equipment available in his section

He must shut off all power, gas, steam, and any piped solvent/gases in the affected area, if possible.

He will take a roll call at the assembly point.

Squad Leader

On hearing the alarm, he will proceed to the Emergency Control Point or place of incident whichever is closer.

He will take instructions from the Main Controller or, in his absence the Incident Controller and organize his Fire Fighting squad accordingly.

He will assist the outside agencies involved as per instructions of the Incident Controller.

Communication In-charge

He will immediately report to the Main Controller at the Emergency Control Point on hearing the alarm.

He will inform outside emergency services as per instruction of the Main Controller like the Fire Brigade, Police, Bomb Disposal Squad, Hospital / Ambulance services etc. and liaise with them.

Manager (Engineering)

He will report to the Main Controller at the Emergency Control Center along with one Electrician, one Mechanic and four General Workers for salvage operations.

He will take appropriate action for protection of the boilers, Generators, and high Pressure gas pipeline mains.

He will insure that necessary services to the unaffected areas to be continued

On instruction of the Main Controller, he will arrange removal of any equipment etc. which may be affected by the incident.

Manager (Human Resource)

He will prepare the nearby Hospital to receive casualties.

He will have stretchers sent to the affected areas, if required.

He will ensure availability of emergency vehicles for further evacuation to hospitals, if required.

Security Officer

He will be responsible for the evacuation of any guests or other visitors inside the Plant.

He will ensure that all Plant gates are secured by Security Guards.

He will ensure that no unauthorized person enters the premises through any gate.

He will ensure that entry of any personnel into the premises will be recorded.

Emergencies

Spillage of Liquid / Solids

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Raw Material, intermediates, Finished Goods etc.

On discovering a spillage, the following actions should be taken:

Raise the Alarm:

Any person discovering a spillage must raise the alarm. Either verbally, if it is a small spillage, or in the event of a major spillage the Plant Alarm System and / or inform the personnel as indicated in the Section 1.00

If any doubt about the scale of the spillage, then treat it as major spillage.

It is important that the spill material is identified as quickly as possible to ensure that correct actions are taken in treating the spillage.

Evacuate Personnel:

All unprotected personnel must be immediately evacuated from the affected area and medical assistance must be provided for anyone exposed to chemicals.

Anyone trapped in the affected area must be rescued as soon as possible by suitably protected personnel.

Isolation:

As soon as possible, but only when wearing the appropriate PPE, the source for the spill must be isolated. This may mean closing a valve, up-righting a container, etc.

Act quickly but safely to minimize the spill.

Remember when the fire alarm is activated the Plant is put into the FAIL-SAFE condition and most drives will be stopped and valves put into a safe state.

Contain and Treat:

It is very important that the spill is kept to as small an area as possible by using the spillage equipment provided. Containment is possible by damming and blocking the flow. It is essential that drains are protected by using sand or absorbent pads and sock cleaning pads etc.

Clean-up and De-contaminate:

Any material used in the treatment of the spillage must be treated as contaminated waste and disposed off as it is. Tools or equipment must be thoroughly decontaminated.

Decontamination of the surfaces of equipment and affected areas of the Plant is essential and must be carried out as per relevant *Material Safety Data Sheet* and the equipment checked before use.

First Aid:

In case any person has come in contact with any hazardous chemicals, the general first aid that can help is immediate washing of the affected part of the body with copious amount of water.

Further air can be given as per instructions specific to the chemical and listed in the *Material Safety Data Sheet*.

Emergency due to Gas Vapors

This can occur on its own or be the result of spillage of a volatile solvent, which may form a hazardous vapor cloud.

On discovering a leakage, the following actions should be taken:

Raise the Alarm:

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Person discovering a leakage must raise the alarm. Either verbally, if it is a small leakage, or in the event of a major leakage the Plant Alarm System and / or inform the personnel as indicated in Section 1.00

If in doubt about the scale of the leakage, then treat it as major leakage.

It is important that the material leaking is identified as quickly as possible to ensure that the correct actions are taken in controlling the leakage.

Evacuate Personnel:

All unprotected personnel must be immediately evacuated from the affected area and medical assistance provided for anyone exposed to leakage.

Anyone trapped in the affected area must be rescued as soon as possible by suitably protected personnel.

Isolation:

As soon as possible, but only when wearing the appropriate PPE, the source for the leakage must be isolated. This may mean closing a valve, etc.

Act quickly but safely to minimize the leakage.

Remember when the fire alarm is activated, the Plant is put into the FAIL-SAFE condition and most drives will be stopped and valves put into a safe state.

The Wind direction should be noted, and if necessary go inside the enclosed area.

The Main Controller should decide if the volume of Gas / Vapor is significant to be harmful outside the Plant. If so, the Security Officer will be sent on available transport to warn the inhabitants of oncoming vapors.

The Gas vapor clouds can be countered with water jets from the nearest fire hydrants. The resulting solution may then be limited by damming with sand.

In case the material is hazardous, evacuation and all other emergency procedure are to be activated as identified in Section 1.00 of this manual.

First Aid:

In case any person has come in contact with any hazardous vapors of chemical, the general first aid that can help is immediate washing of the affected part of the body with copious amount of water.

Further air can be given as per instructions specific to the chemical and listed in the *Material Safety Data Sheet*.

Emergencies due to Heavy Rain or Dust Storm

Thunderstorms, with or without heavy rainfall, frequently occur in Rawalpindi/Islamabad and are usually not serious enough to cause any emergency situations. However, in the event of it being considered potentially serious, necessary actions must be taken to prevent losses.

All doors and windows of building to be shut.

The Animal House breeding area to be covered with available tarpaulins. These should be tied down with ropes if the wind is very strong.

If the water begins to collect within the Plant area and the level raises to more than one foot, all electrical, connections to be switched off except for the Plant Street lights.

All valuable equipment, material and records should be placed as high as possible.

If there is a danger of the road blockage, the workers should be allowed to leave the Plant.

After the storm is over, the departmental heads should be asked to evaluate any damage caused and submit reports to the Managing Director.

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It is important that the material leaking is identified as quickly as possible to ensure that the correct actions are taken in controlling the leakage.

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The Manager (Engineering) should survey the Plant, checking the wiring system, equipment etc. and issue certificates of worthiness before the equipment is switched on.
The Manager (Engineering) should also prepare a repair program based on his survey.

Emergency due to Bomb Threat

The threat of having a hidden bomb in the Plant premises may come in on the phone at any of the mentioned in Appendix 3.04:

Even though this threat may be a hoax, it must be taken seriously and necessary actions must be taken.

If possible tell someone else immediately so that they can tell the Main Controller. **DO NOT PUT DOWN THE HANDSET OR STOP THE CONVERSATION.** Try to keep the caller talking. Get as much information as you can, fill in the Check List available in your offices comprising of following questions:

- Time of Call
- Where is the bomb?
- What time will it go off?
- What does it look like?
- What kind of explosive is in the bomb?
- Why are you doing this?
- Who are you?

When the call has finished give the information to the Main Controller or the most senior officer available. If no such person is available, contact the "Sihala Police Station". It should be dealt with immediately. The more information you can get the easier it will be to decide whether the warning was serious or not.

After giving the information, fill in the second part of the check list comprising of the following questions:

- Was the Caller Male / Female / Child / Young / Old / Don't know.
- How they sounded Drunk / Rational / Rambling / Laughing / Accent / Speech Impediment (if yes give details)
- Was the caller reading the message Yes / No
- Other noises during the call any noise on the phone line? / yes / no / if yes give details
- Did the caller use pay phone Yes / No
- Did you hear the operator Yes / No
- Was there any interruption to the call Yes / No, if yes give details
- Other noise in the background Traffic / Talk / Typing / Machinery / Air Craft/ Music / children any other
- Number you received on the call _____
- Your name _____

The Main Controller or any Manager receiving the information will immediately contact the Bomb Disposal Squad as well as Sihala Police Station on Telephone Numbers mentioned in Appendix 3.01

The Main Controller or in absence of any Main Controller, any senior officer receiving an information call a meeting of all available managers and jointly decide on a course of action.

In case it is felt necessary to evacuate personnel from all or part of the Plant, the evacuation procedure outlined in Section 02 of this manual must be followed

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In case of any emergency, no one will deal with the media, except the spokesman appointed by the Managing Director

Response due to Major Fires

When

When any employee(s) notice a fire, he/she must immediately decide if the nature of the fire is such that he/she could take action on his/her own for extinguishing it while simultaneously raising a verbal alarm for help. Quite often, a timely act can avert the major outbreak.

If it is considered to be beyond the scope of individual action, the alarm should be raised as follows:

- Activate the nearest Fire Alarm switch. At the moment these alarm switches are available as mentioned in Appendix 3.1.4
- Where such an alarm switch is not provided, he should run to the Admin Office shouting Fire! so as to warn other colleagues. Anybody hearing the shout will immediately activate nearby Fire Alarm switch.
- The Security Officer will immediately inform the Plant Manager or any other Manager, if he is not present.

Fire Squad

Immediately on hearing the fire alarm all members of the Fire Squad will rush towards the squad assembly point in front of the Production Manager Office. Till the time that further directions are received from Fire Squad Leader the squad will draw equipment from the room. The squad will then proceed to the scene of fire and start action as guided by the Fire Squad Leader.

All Security Staff is permitted to leave their place of duty if fire alarm is raised, except one guard at Main Gate who will not leave his post. He will direct any outside agency to the fire location.

"Off Duty" security staff will also report immediately for duty.

Area Supervisor

Till such time that the Fire Squad reaches the scene, the Area Supervisor will as far as possible initiate fire fighting procedures and arrange evacuation, if necessary. They shall guide staff to the exit and assembly points.

Essential Points in Fire Fighting

It should be noted that quick action can quite often save the situation. Remember that to put out a fire following requirements are important:

- Don't endanger yourself
- Cool down fire and surrounding areas
- Prevent supply of air for oxidation

Runners

Individual area supervisors will remain in contact with the Fire Squad Leader, through use of runners for purpose of receiving instructions with regard to evacuation and any other/ assistance required from them.

Service / Actions required in case of Fire

If required by the Fire Squad Leader, the Area Supervisor will initiate the following actions for his department / section.

Controlled Copy: Not to be duplicated

FLOW CHART OF REVERSE OSMOSIS PLANT

RAW WATER FEED PUMP
To Suck & Deliver Raw water for further treatment

Sand FILTRATION
Water passes thru media for further treatment

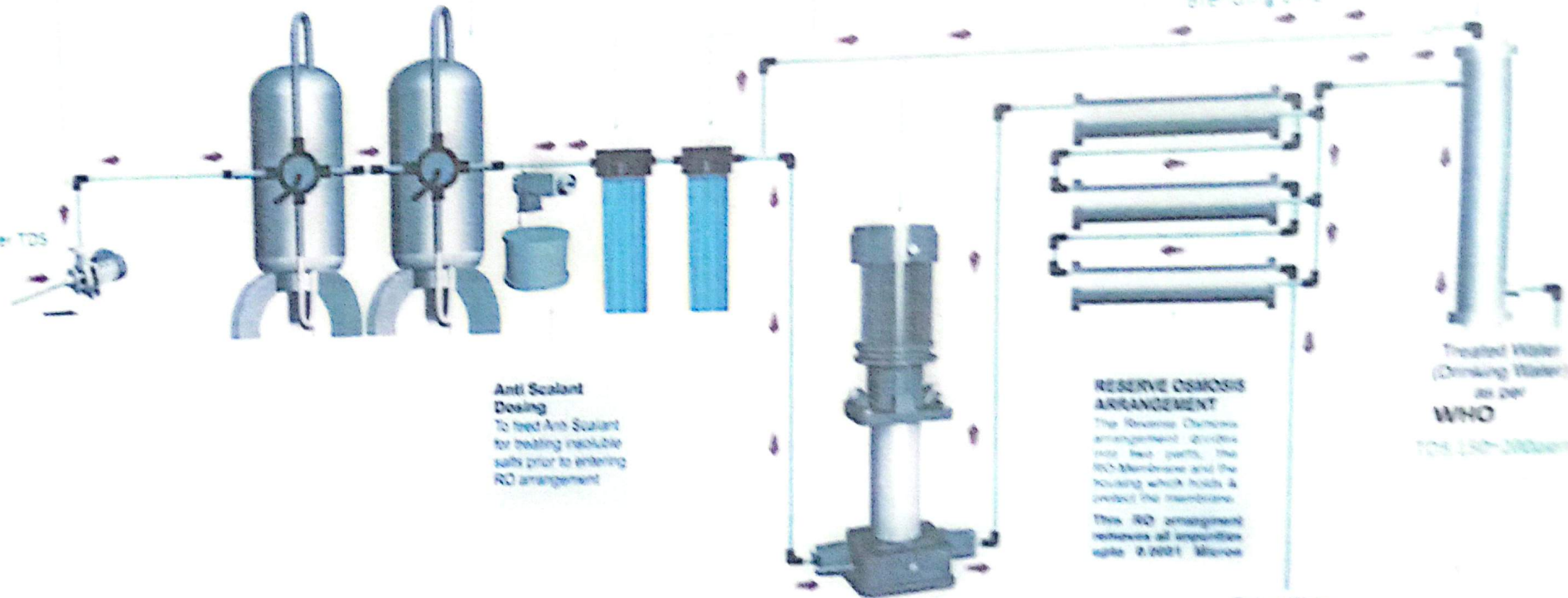
Carbon FILTRATION
To filter suspended & organic impurities

MICRON FILTRATION
To filter residual suspended impurities up to 5 Micron

HIGH PRESSURE PUMP
This Stainless steel High Pressure Pump is to Boost Pressure upto 16 kg/cm²

UFM STERILIZATION
System is to remove Biological Contamination and is capable to destroy Bacteria & Virus up to 99.9%

Raw Water TDS 785 ppm



Anti Scalant Dosing
To feed Anti Scalant for treating insoluble salts prior to entering RO arrangement

REVERSE OSMOSIS ARRANGEMENT
The Reverse Osmosis arrangement consists into two parts, the RO Membrane and the Housing which holds & protect the membrane.
This RO arrangement removes all impurities upto 0.001 Micron

Treated Water (Drinking Water) as per WHO
TDS 140-300ppm

Reject Water
Can be used for Gardening, Washing etc.