

**ESTABLISHMENT OF IVD MEDICAL DEVICES MANUFACTURING
FACILITY BY M/S APEX BIOTECHNOLOGIES
PLOT NO. 08, CENTRAL ROAD, RAWAT, RAWALPINDI**

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**ENVIRONMENT IMPACT ASSESMENT REPORT
(EIA)**

PREPARED BY



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EXECUTIVE SUMMARY

M/S Apex Biotechnologies proposes to establish a modern In-Vitro Diagnostic (IVD) manufacturing facility at Plot No. 8, Central Road, Rawat Industrial Area, Rawalpindi. The project is strategically planned to meet the growing demand for reliable diagnostic products in Pakistan while reducing dependence on imported kits and reagents. Designed in full compliance with Good Manufacturing Practices (GMP) and the regulatory framework of the Drug Regulatory Authority of Pakistan (DRAP), the unit will ensure the production of high-quality, safe, and cost-effective diagnostic solutions. The facility will be equipped with dedicated sections for bulk reagent formulation, vial filling, labeling, and automated packaging of diagnostic kits. Reagents will be prepared in controlled batch sizes of 20 liters, 5 liters, and 1 liter, ensuring flexibility in production and strict adherence to quality standards. Finished products will include ELISA kits, PCR reagents, rapid test buffers, and other laboratory consumables, which are widely used in clinical laboratories, hospitals, and research institutions for disease detection and healthcare diagnostics. To guarantee product integrity and regulatory compliance, the project will feature state-of-the-art Quality Control (QC), microbiology, stability testing, and In-Process Quality Control (IPQC) laboratories. Infrastructure facilities such as HVAC-controlled clean rooms, purified water and WFI systems, effluent treatment, and fire safety installations will be incorporated to create a safe, compliant, and sustainable manufacturing environment. Adequate warehousing and storage facilities will also be developed to maintain inventory under prescribed environmental conditions.

In addition to improving the availability of reliable diagnostic kits, the project will contribute significantly to the healthcare resilience of Pakistan, ensuring timely access to essential diagnostic tools at affordable costs. The initiative will also generate direct and indirect employment opportunities, promote local industrial growth, and support the government's broader vision of enhancing healthcare self-sufficiency through import substitution and local manufacturing. Overall, the proposed facility represents a critical step towards strengthening Pakistan's diagnostic sector by delivering high-quality, locally produced IVD kits that meet both national and international standards, while simultaneously supporting the economy and public health.

I. Need of the Project

The main objective of the project is to establish a purpose-built, state-of-the-art In-Vitro Diagnostic (IVD) manufacturing facility that ensures the production of reliable, safe, and affordable diagnostic kits and reagents in compliance with Good Manufacturing Practices (GMP) and Drug Regulatory Authority of Pakistan (DRAP) regulations, while supporting healthcare resilience, patient safety, and local industrial development.

The project is necessary to:

- **Ensure Self-Reliance in Diagnostic Kits Production:** By manufacturing a wide range of IVD reagents and kits locally, the facility will reduce dependence on imports and ensure a consistent supply of essential diagnostic tools.

- **Strengthen Healthcare Resilience:** The availability of locally manufactured, GMP-compliant IVD kits will improve Pakistan’s capacity to respond effectively to disease outbreaks, epidemics, and public health emergencies.
- **Promote Quality and Compliance:** The purpose-built facility with advanced quality control, microbiology, and stability testing laboratories will ensure adherence to national and international standards, thereby building confidence among laboratories, healthcare providers, and patients.
- **Support Socio-Economic Development:** The project will create direct and indirect employment opportunities, stimulate industrial growth, and contribute to the local economy, while fostering skill development in biotechnology and diagnostic sciences.
- **Encourage Export Potential:** By meeting stringent international quality standards, the facility will enable Pakistan to compete in the global diagnostics market, thereby supporting foreign exchange earnings and enhancing the country’s reputation in healthcare manufacturing.

II. Policy, Legal and Administrative Framework

The project is required to comply with all applicable environmental policies, laws, acts, and guidelines of the Government of Pakistan and the Government of Punjab, along with relevant international environmental standards. Key regulations include the Pakistan Environmental Protection Act, 1997; Punjab Environmental Protection (Amendment) Act, 2012; Punjab Environmental Quality Standards (PEQS); and relevant rules and notifications issued by the Punjab Environmental Protection Agency (Punjab-EPA). In addition, the project will adhere to the requirements of the Drug Regulatory Authority of Pakistan (DRAP) for Good Manufacturing Practices (GMP) and quality compliance. Where applicable, the project will also align with international best practices for pharmaceutical manufacturing, clean-room operations, effluent treatment, and occupational health and safety.

III. Environment Category of the Project

Based on the Punjab Environmental Protection Act 2012 and the Review of IEE & EIA Regulations, 2022 for filing, reviewing, and approving environmental assessments, the present project is classified under Schedule II class B (2).

IV. PROJECT TITLE AND LOCATION

Title: Establishment Of IVD Medical Devices Manufacturing Facility By M/S Apex Biotechnologies at Plot No. 08, Central Road, Rawat, Rawalpindi.

Location: Plot No. 08, Central Road, Rawat, Rawalpindi.

V. Project Proponent

Mr. Muhammad Sohail Nawaz is the proponent of proposed project & wants to get NOC for compliance of Section 12 to establish its business.

Name	Muhammad Sohail Nawaz
CNIC	35202-73203539-1

VI. The EIA Study Consultant



Climate Caretakers

Office: 218 Upper Mall Scheme Lahore, Pakistan.

VII. Brief Description of the project

The proposed IVD Medical Devices Manufacturing Unit is a purpose-built, state-of-the-art facility designed to produce a wide range of high-quality diagnostic kits and reagents in compliance with Good Manufacturing Practices (GMP) and Drug Regulatory Authority of Pakistan (DRAP) regulations. The facility will include multiple dedicated production sections, namely the bulk reagent preparation area, buffer preparation area, ELISA kit assembly line, PCR reagent preparation and filling section, and rapid test kit assembly section, with appropriate segregation to ensure product integrity and prevent cross-contamination. In support of these operations, the unit will be equipped with a comprehensive quality infrastructure, comprising a Quality Control (QC) laboratory, Microbiology laboratory, Stability Testing laboratory, and In-Process Quality Control (IPQC) laboratory, enabling strict monitoring of raw materials, in-process samples, and finished products. Adequate storage facilities will be provided, including controlled raw material storage, finished goods storage, and packaging material storage, designed in accordance with international standards for temperature and humidity control. The facility will be fitted with modern clean-room environments, HVAC-controlled production areas, purified water systems, effluent treatment facilities, and fire safety provisions to maintain a controlled, compliant, and safe manufacturing environment. By ensuring the local availability of reliable, safe, and affordable diagnostic devices, the project will not only enhance healthcare capacity but also contribute to import substitution, healthcare resilience, and socio-economic development in Pakistan.

VIII. Project Impacts and Recommendations for their Mitigation

Impact assessment is crucial for project initiation as it enables the identification and comprehension of a project's potential positive and negative effects. Understanding these impacts aids in tailoring the project to maximize benefits and minimize risks. Impact assessment assists in recognizing environmental, social and economic challenges and risks and gives the directions to develop strategies that mitigate these risks and adjust the plan accordingly.

Table A 1 : Project Impacts and their Mitigations Measure

Screening of possible Impacts during Design/Pre- Construction phase

S/No.	Potential Issue	Likelihood	Consequence	Risk Level	Residual Impact
1	Improper facility design not meeting GMP / DRAP standards for IVD manufacturing	Unlikely	Major	Medium	Long Term
2	Incorrect siting near sensitive receptors (residential/schools/hospitals)	Rare	Major	Medium	Long Term
3	Use of substandard construction materials or non-certified equipment	Likely	Moderate	Medium	Long Term

4	Inadequate fire safety & emergency systems in design	Possible	Major	High	Long Term
5	Occupational health & safety risks during site clearing and preparation	Likely	Moderate	Medium	Short Term
6	Community disturbance (dust, noise, traffic) during pre-construction	Likely	Minor	Low	Short Term

Screening of possible Impacts during Construction phase

S/No.	Potential Issue	Likelihood	Consequence	Risk Level	Residual Impact
1	Dust emissions from excavation, material handling, and vehicle movement	Likely	Moderate	Medium	Short Term
2	Noise and vibration from construction machinery and equipment	Likely	Minor	Low	Short Term
3	Improper disposal of construction debris and packaging waste	Possible	Moderate	Medium	Medium Term
4	Accidental spillage of fuels, lubricants, or construction chemicals	Possible	Major	High	Medium Term
5	Increased traffic and congestion from material and equipment transport	Likely	Minor	Low	Short Term
6	Occupational health and safety risks to construction workers	Likely	Major	High	Short Term
7	Disturbance to nearby communities due to dust, noise, and traffic	Possible	Moderate	Medium	Short Term
8	Improper storage of construction materials leading to contamination/fire	Unlikely	Major	Medium	Medium Term
9	Accidental damage to utilities (water, electricity, telecom lines)	Rare	Major	Medium	Short term

Screening of possible Impacts during Operational Phase

S/No.	Potential Issue	Likelihood	Consequence	Risk Level	Residual Impact
1	Air emissions from generators and HVAC systems	Likely	Moderate	Medium	Long Term
2	Improper treatment/disposal of biomedical/chemical effluents from reagent preparation	Possible	Major	High	Long Term
3	Solid and hazardous waste mismanagement (expired reagents, plastic consumables, packaging waste)	Likely	Major	High	Long Term

4	Cross-contamination between diagnostic kit production areas due to poor controls	Unlikely	Major	Medium	Long Term
5	Noise from continuous operation of HVAC, compressors, and machinery	Possible	Minor	Low	Long Term
6	Occupational health risks to workers (chemical exposure, ergonomic strain, accidental spills)	Likely	Major	High	Long Term
7	Fire hazards from storage of flammable chemicals and reagents	Possible	Major	High	Long Term
8	High energy and water consumption (purified water, HVAC demand) impacting resource sustainability	Likely	Moderate	Medium	Long Term
9	Community complaints due to emissions, noise, or transport activities	Possible	Moderate	Medium	Long Term
10	Non-compliance with GMP, DRAP, or biosafety standards	Rare	Major	Medium	Long Term

IX. PROPOSED MONITORING

The monitoring program is designed to ensure that the requirements of the environmental approval awarded by the EPA are met. Monitoring Program (MP) provides important information that allows for more effective planning and an adaptive response based on the assessment of the effectiveness of mitigation measures. The monitoring of various parameters will help to determine the extent to which project construction/operation activities will cause an environmental disturbance.

Table A 2: Proposed Monitoring Plan

Environmental segment/element	Monitoring parameters	Reference location/monitoring point	Monitoring frequency
Construction Phase			
Water Quality	As prescribed by the Punjab environmental Drinking Water Quality Standards	Main Drinking Water Source	Quarterly
Ambient air emissions	Dust, Smoke, PM, SO _x , NO _x , CO	Use of generators, movement of materials, digging or	Quarterly

		excavation.	
Waste water including Sewage	Ensure that all wastewater is treated to the level set by the PEQS.	The sewage or sanitary wastewater by the campsite and use for other construction activities.	Quarterly
Noise	The Levels prescribed as in Punjab environmental quality standards	The noise produced by the machinery during construction work.	Quarterly
Solid Waste Disposal	Ensure that all wastes are disposed of according to legal requirements of the country.	The waste material, rubble and solid waste produced by the camp site	Quarterly
Operational Phase			
Water Quality	As prescribed by the Punjab environmental Drinking Water Quality Standards	Main Drinking Water Source	Quarterly
Ambient air emissions	Methane and carbon dioxide, PM, CO, O3	Generator Area	Quarterly
Waste water including Sewage	Ensure that all wastewater is treated to the level set by the PEQS- Pakistan.	Main Disposal Site	Quarterly
Noise	Noise levels	Generator and parking area	Once monthly at all involved places
Solid Waste Disposal	Ensure that all wastes are disposed of according to legal requirements of the country.	Building's solid waste/ storage area	Regularly in connection with environmental and safety rounds.

X. **Environmental Management Cost**

The cost for environmental management and monitoring will be the part of contract of Contractor and Consultants respectively. However, a lump sum amount will be allocated by the project proponent as cost for environmental training and monitoring for a period of two years during construction and operation of the project.

Table A 3: Environmental Management Cost

Sr. No.	Environmental Management / Monitoring Item	Cost (PKR)
1	Air Quality & Noise Monitoring (annual)	150,000
2	Water Quality Testing (process + drinking)	150,000
3	Effluent / Wastewater Testing	100,000
4	Solid & Hazardous Waste Management (bins, disposal contracts)	200,000
5	PPE & Safety Equipment for Workers	150,000
6	Training & Awareness Programs (environmental, biosafety)	100,000
7	Emergency Preparedness (spill kits, first aid, firefighting)	100,000
8	Environmental Reporting & Compliance (EPA fees, consultant audits)	150,000
Total	—	1,000,000

XI. Stakeholder Consultations

Consultations were conducted with the inhabitants of the surrounding area regarding the proposed IVD medical devices manufacturing facility. The community members expressed a positive attitude towards the project and welcomed its establishment in their locality. They viewed the facility as a healthcare-supportive initiative that would contribute to improving diagnostic services in the region by ensuring the availability of locally manufactured reagents and solutions. Stakeholders also appreciated the potential for employment opportunities, skill development, and local economic growth. According to the feedback received, people perceived the project as a step towards strengthening the healthcare sector at the local level, reducing reliance on imported diagnostic materials, and contributing positively to the overall social and environmental development of the area

XII. Conclusion

The study was undertaken to assess the potential environmental issues associated with the establishment of the proposed APEX Biotechnology IVD Medical Devices Manufacturing Facility. All relevant environmental impacts have been identified through baseline studies and field assessments, and suitable mitigation measures have been proposed in the report. The IEE/EIA has been conducted in accordance with the Pakistan Environmental Protection Act, 1997, the Punjab Environmental Protection

(Amendment) Act, 2012, and the applicable Punjab Environmental Quality Standards (PEQS).

In light of the findings, it is envisaged that the establishment and operation of the IVD medical devices manufacturing facility will significantly contribute to the local availability of high-quality diagnostic reagents and solutions, thereby strengthening healthcare services in the region. With the effective implementation of the proposed environmental management and mitigation measures, the project will not pose any major adverse environmental or social impacts.

On the contrary, the project is expected to deliver substantial positive benefits through improved healthcare support, employment generation, skills enhancement, and local economic growth. By reducing dependency on imported diagnostic materials and fostering indigenous manufacturing capacity, the project will also contribute to healthcare resilience and sustainable development.

Furthermore, the project enjoys strong community and stakeholder support, given its importance in improving access to reliable diagnostic tools and enhancing the overall health infrastructure of the area.

1 Introduction

The healthcare sector in Pakistan is rapidly evolving, with an increasing demand for reliable and cost-effective In-Vitro Diagnostic (IVD) medical devices. Diagnostic reagents and buffer solutions play a vital role in the detection, monitoring, and prevention of diseases by supporting accurate laboratory testing and clinical decision-making. At present, much of the country's demand for IVD reagents is met through imports, which are costly, time-consuming, and susceptible to supply chain disruptions.

To address this gap, APEX Biotechnology proposes the establishment of an IVD Medical Devices Manufacturing Facility on a land area of approximately 2 kanal. The project aims to produce high-quality diagnostic reagents, buffers, and solutions for use in clinical laboratories, hospitals, and healthcare institutions. By focusing on indigenous manufacturing, the project will enhance the availability, affordability, and reliability of essential diagnostic products in Pakistan.

The facility will be equipped with modern mixing, formulation, filling, and packaging systems, supported by quality control laboratories and environmental management measures to ensure compliance with regulatory standards, including the Pakistan Environmental Protection Act, 1997 and Punjab Environmental Quality Standards (PEQS). Beyond strengthening the healthcare supply chain, the project is expected to bring positive socioeconomic impacts, including employment generation, skill development, and local economic growth, while maintaining sustainable and environmentally responsible operations.

To fulfil the legal requirements under Section 12 of the Punjab Environmental Protection Act (Amended 2012), this Initial Environmental Examination (IEE)/Environmental Impact Assessment (EIA) report is submitted. The study evaluates the potential environmental and social impacts of the proposed facility during both the construction and operational phases, while also recommending suitable mitigation and environmental management measures to ensure the project remains environmentally responsible and sustainable.

1.1 Purpose of the Report

As per the Punjab Environmental Protection Act (PEPA), Section 12, which covers Initial Environmental Examination and Environment Impact Assessment, no project proponent is allowed to initiate construction or operations without filing the necessary documentation with the designated Government Agency under the Provincial Environmental Agencies. If the project is anticipated to cause adverse environmental effects, it necessitates an environmental impact assessment. Subsequently, approval must be obtained from the Government Agency. This requirement set forth by the Government of Punjab mandates the preparation of this Environmental Impact Assessment (EIA) Report to secure Environmental Approval (EA) from the Environmental Protection and Climate Change Department (EPA), Government of Punjab (GoP), Lahore.

This report provides comprehensive information and data on the environmental, economic, and social impacts of the project, enabling its assessment and justification that the project will comply with the requirements of environmentally sustainable practices during both installation and operation stages, as required by the Punjab Environmental Protection Act, 2012, the Punjab Environment Quality Standards, and the rules and regulations thereof.

1.2 Identification Of Project And Proponent

Title:The proposed project is the Establishment of the In-Vitro Diagnostic (IVD) Medical Devices Manufacturing Facility by APEX Biotechnology.

Proponent: The details of the proponent are as following:

Name	Muhammad Sohail Nawaz
CNIC	35202-73203539-1

1.3 Details of Consultant



Climate Caretakers

Office: 218 Upper Mall Scheme Lahore, Pakistan.

1.4 Brief description of nature, size and location of project:

The proposed project is the establishment of an In-Vitro Diagnostic (IVD) Medical Devices Manufacturing Facility by APEX Biotechnology, aimed at producing a wide range of diagnostic reagents, buffers, and chemical solutions essential for medical testing and laboratory analysis. These products are critical components of diagnostic kits used in hospitals, clinical laboratories, and healthcare institutions for disease detection, monitoring, and treatment support. The facility is designed to reduce dependency on imported reagents by providing locally manufactured, high-quality, and affordable diagnostic solutions.

The nature of the project is primarily industrial and healthcare-oriented, focusing on the formulation, quality testing, and packaging of IVD reagents. The production process will involve mixing of raw materials in controlled environments using 20-liter, 5-liter, and 1-liter batch preparation systems, followed by automated filling, labeling, and carton packaging machines. Supporting facilities such as a quality control laboratory, storage and warehousing units, HVAC systems, and water purification plants will ensure that the products meet international diagnostic standards.

The size of the project is planned to cover an area of approximately 2 kanal (\approx 9,000 sq. ft.). This area will be utilized for the construction of production halls, QC and R&D laboratories, storage facilities, administrative offices, and utility blocks. The plant has been designed to optimize space utilization while maintaining compliance with Good Manufacturing Practices (GMP) and environmental regulations.

The location of the project is Plot no. 8, central road, Rawat, Rawalpindi, selected for its strategic advantages such as availability of utilities (electricity, water, and gas), road connectivity for transportation of raw materials and finished products, and a safe distance from densely populated residential areas. The site's accessibility to local healthcare markets and distribution networks makes it ideal for setting up a specialized manufacturing facility. Moreover, the location allows for proper waste management and environmental safeguards, minimizing any potential adverse impacts on the surrounding environment.

In summary, the project represents a medium-scale industrial healthcare initiative, contributing towards healthcare strengthening, employment generation, and import substitution, while ensuring compliance with national environmental and regulatory standards.



Figure 1-1: Location Map of the project area

2 Screening of the Project

Based on the Punjab Environmental Protection Act 2012 and the Review of IEE & EIA Regulations, 2022 for filing, reviewing, and approving environmental assessments, the present project is classified under Schedule II class B (2). Following list shows the projects included in Class B.

A. Manufacturing and Processing

1. Cement plant
- 2. Chemical manufacturing units, including pharmaceuticals and cosmetic**
3. Sugar mills and Distilleries
4. Food processing industries including, beverages, milk and dairy products with total cost more than Rs 200 million
5. Paper and paperboard, paper pulping, paints and dyes,
6. Textile units comprising of dyeing & printing
7. Pesticides and fertilizer manufacturing units
8. Poultry waste processing units / rendering units
9. Tannery and leather units
10. Rubber projects with total cost more than Rs. 100 million
11. Battery Manufacturing and Recycling Plants
12. Ceramics and glass units
13. Electro plating and nickel/chrome plating including Surgical Units
14. Cutlery units
15. Slaughter House
16. Iron and steel rolling mills
17. Steel Furnaces
18. Smelting plants
19. Auto mobile manufacturing and assembling units
20. Resource Recovery Units

The establishment of the proposed APEX Biotechnology IVD Medical Devices Manufacturing Facility requires an Environmental Impact Assessment (EIA/IEE) due to the nature of its operations and potential impacts on air, water, soil, and occupational health. The assessment is essential to ensure compliance with the Pakistan Environmental Protection Act, 1997 and the Punjab Environmental Protection (Amendment) Act, 2012, while addressing environmental protection, healthcare safety, and regulatory obligations. Through this study, potential environmental and social impacts are identified, and appropriate mitigation measures are proposed for the design, construction, and operational phases. The EIA/IEE also facilitates informed decision-making, transparency, and stakeholder participation, ensuring that the project is developed in a sustainable and environmentally sound manner.

3 Scoping of the project

The scoping process outlines the essential concerns and impacts requiring detailed investigation. It establishes the spatial and temporal limits, crucial concerns raised during consultations, and significant impacting factors impacting the project.

3.1 Spatial and Temporal Boundaries of Environmental Assessment

Considering spatial and temporal boundaries in environmental assessments is vital to comprehensively evaluate the impact of a project. Spatial boundaries define the area affected, aiding in recognizing the extent of impact on ecosystems and nearby communities. Temporal boundaries assess short and long-term effects, enabling an understanding of how impacts evolve over time and helping in planning mitigation measures and long-term sustainability strategies. This approach ensures accurate, detailed assessments and effective addressing of potential environmental consequences related to the project. The proposed project is located at Plot no. 8, central road, Rawat, Rawalpindi.

3.2 Important issues and concerns raised during consultation

The EIA for the proposed project incorporated a two-stage consultation process, primarily focused on one-on-one meetings. In the initial stage, the consultation was specifically directed towards engaging local government authorities, affected individuals, and local communities. The primary goal of this stage was to evaluate both the short-term and long-term impacts that might result from the new development proposed for the project in its early stages. The intent was to gather insights and perspectives from key stakeholders in the immediate vicinity to better understand potential environmental, social, and economic implications of the project.

The second stage of consultations, as indicated, will be conducted through a more extensive process of public participation if deemed necessary. This broader involvement will allow for a wider outreach to the public, enabling a more comprehensive engagement to gather additional feedback, concerns, and insights from a larger cross-section of the community. This will ensure a more inclusive approach, providing an opportunity for a wider range of stakeholders to contribute their perspectives, concerns, and suggestions, which can be valuable in shaping and refining the EIA for the proposed project.

3.3 Significant impacts and factors to be determined

In an IVD medical devices manufacturing facility, the determination of significant impacts requires a careful assessment of the environmental, occupational, and public health risks associated with the handling of chemical reagents, preservatives, surfactants, and buffer components used in diagnostic formulations. Key factors to be considered include the potential for air and water pollution, generation of chemical and laboratory waste, energy and water consumption, and emissions from HVAC systems and laboratory processes.

Occupational health and safety risks for workers, such as exposure to chemical substances, handling of laboratory-grade reagents, and operation of mixing, filling, and packaging equipment, also need close evaluation. Impacts on surrounding communities, the adequacy of local infrastructure, and compliance with national environmental standards must be assessed as part of the study.

In addition, emergency preparedness, spill containment measures, safe waste disposal systems, and biosafety protocols are critical to ensuring sustainable operations. Adherence to

Good Manufacturing Practices (GMP) and relevant regulatory guidelines, including those of DRAP and PEQS, is essential to minimize risks. Identifying and addressing these impacts is vital for protecting human health, safeguarding the environment, and ensuring regulatory compliance throughout the lifecycle of the IVD manufacturing facility.

3.4 Development of an Environmental Management Plan

The EMP in an EIA is crucial as it outlines strategies to mitigate environmental impacts, ensures regulatory compliance, guides project operations, promotes sustainability, reduces risks, assures stakeholders, and allows for ongoing improvement and adaptation to address environmental concerns throughout the project's lifecycle.

These key parts of EMP include a clear description of the project, an outline of potential environmental impacts and risks, specific mitigation measures tailored to address these impacts, a comprehensive monitoring and reporting system to track environmental indicators, protocols for emergency response and contingency planning, details on stakeholder engagement and communication strategies, and a framework for ongoing review and updates to ensure the plan's adaptability and effectiveness over the course of the project. Together, these components form a comprehensive EMP designed to guide environmental practices, minimize adverse impacts, and maintain compliance with regulations and best practices in environmental management.

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4 Project Alternatives

The alternatives for the proposed project and their relative potential impacts on the environment were considered to evaluate the best project option. The following alternatives were assessed for the project.

Project Alternatives

- No Project Option / Worst Scenario Option
- Site Alternative
- Technology Alternative

4.1 No Project Option / Worst Scenario Option

4.1.1 Analysis

- **Strengths and Opportunities**

If the proposed IVD Medical Devices Manufacturing Facility by APEX Biotechnology is not established, financial resources, time, and human effort invested by the proponent will be preserved and may be redirected to other ventures. There will be no construction-related disturbances such as noise, dust emissions, or traffic congestion. Additionally, the risk of chemical handling, laboratory waste generation, or resource consumption (water, electricity) associated with manufacturing operations would be avoided. The surrounding area would remain unaffected, and the current environmental equilibrium would be maintained.

- **Weaknesses and Threats**

Not proceeding with the project would lead to the loss of significant socio-economic and healthcare-related benefits. Local employment opportunities, technology transfer, and industrial growth would be foregone. Pakistan's dependence on imported diagnostic reagents and buffers would continue, increasing costs and exposing the healthcare system to supply chain disruptions, particularly during public health crises. The opportunity to establish a local, environmentally compliant, and quality-driven IVD manufacturing facility would be missed. Furthermore, stakeholders supporting the project for its potential healthcare and economic benefits would be disappointed.

4.1.2 Conclusion

The "No Project Option" avoids environmental risks in the short term but sacrifices long-term socio-economic, technological, and healthcare benefits. Therefore, this option is **not recommended**.

4.2 Site Alternatives

The project site, measuring 2 kanal, has been carefully selected by the proponent. The land is owned by the company, eliminating the need for additional land acquisition and simplifying

project implementation. The location has access to required utilities and infrastructure and offers logistical advantages for supply chain management and market access.

Key advantages of the selected site include:

- Located in a semi-industrialized area, reducing land-use conflicts.
- Well-connected to nearby transportation routes, ensuring efficient distribution.
- Availability of essential infrastructure such as water, electricity, and access roads.
- Close proximity to skilled workforce, laboratories, healthcare institutions, and suppliers.

The selected site is not only logistically convenient but also minimizes potential environmental and social disturbances, making it the most suitable option for the facility.

4.3 Technology Alternative

4.3.1 Analysis

In the medical device and diagnostic reagent manufacturing sector, selecting the appropriate production technology and design standards is critical for ensuring product quality, worker safety, and regulatory compliance. For the proposed APEX Biotechnology facility, two broad technology options were evaluated:

4.3.2 Manual Production Systems

- Lower initial capital cost.
- High reliance on labor, with greater chances of error.
- Increased occupational health risks due to direct handling of chemicals.
- Difficult to maintain sterility and compliance with Good Manufacturing Practices (GMP).

4.3.3 Fully Automated Systems

- High precision, sterility, and consistency in reagent preparation and packaging.
- Reduced worker exposure to chemicals, improving occupational safety.
- Significant capital investment required, with higher operational costs.
- Greater reliance on imported technology and specialized expertise.

4.3.4 Proposed Semi-Automated Approach

The selected approach for this facility is a semi-automated production process that integrates automated mixing, filling, and packaging machinery with trained operator supervision. This method ensures:

- Compliance with cGMP and DRAP standards for quality assurance.
- Efficiency and scalability while keeping costs manageable.
- Improved worker safety through minimized direct chemical handling.
- Flexibility for future expansion into more advanced automation.

4.3.5 Conclusion

While both manual and fully automated options were considered, the semi-automated process with cGMP-compliant equipment was chosen. This hybrid approach strikes the best balance between safety, efficiency, regulatory compliance, and cost feasibility. It ensures reliable local production of diagnostic reagents and supports sustainable growth in Pakistan's healthcare and biotechnology sector.

5 Description of the project

This chapter presents all aspects of the proposed project. It details the nature of the proposed project involving the IVD Medical Devices Manufacturing Facility by APEX Biotechnology, its location, designs and site layout/plan. It presents the activities that will be involved during all stages of project; how product will form, detail of process and machinery as well as details on supportive resources i.e. man power and utility requirements. i.e., man power and utility requirements.

5.1 Type & Category of the Project

The proposed project is the establishment of APEX Biotechnology IVD Medical Devices Manufacturing Facility, aimed at setting up a modern, compliant, and environmentally responsible diagnostic reagent production unit. The facility will comprise specialized production sections equipped with mixing vessels of varying capacities (20 L, 5 L, 1 L), semi-automated filling and sealing machines, and a carton packaging line for finished products. To ensure uninterrupted operations, the project also includes dedicated storage facilities for raw materials, chemical reagents, and packaging supplies, alongside secure areas for finished product storage. Comprehensive quality assurance and compliance will be maintained through in-house laboratories for Quality Control (QC), Microbiology, and Stability Testing, designed to meet Good Manufacturing Practices (GMP) and Drug Regulatory Authority of Pakistan (DRAP) guidelines. The facility will be constructed on a 2-kanal site using modern RCC and pre-engineered building (PEB) structures to ensure operational efficiency, safety, and regulatory compliance. With a total estimated project cost of PKR 100 million, the proposed development qualifies as a medium-scale industrial project. As per the Punjab Environmental Protection Act, 2012 and the Review of IEE & EIA Regulations, 2022, the project falls under Schedule II, Class B (2) category, thereby requiring the preparation of a comprehensive Environmental Impact Assessment (EIA) report.

5.2 Objective Of The Project

The primary objective of the proposed project by APEX Biotechnology, located on a 2-kanal site, is to establish a state-of-the-art IVD medical devices and diagnostic reagents manufacturing facility that complies with national and international quality standards, including cGMP and DRAP guidelines. The project aims to strengthen local production capacity of diagnostic kits and reagents, thereby reducing reliance on imported products and improving timely access to essential healthcare tools. By integrating modern semi-automated technologies and stringent quality control systems, the facility will ensure the production of safe, reliable, and high-quality diagnostic products. In addition to supporting the healthcare sector, the project will generate skilled employment opportunities, stimulate economic growth, and contribute to the advancement of Pakistan's biotechnology and medical devices industry.

5.3 Location and Site Layout of the Project

The Location of the proposed project is shown in the figure 5-1 below. The proposed project is located at Plot no. 8, central road, Rawat, Rawalpindi at the following geographic coordinates:

- **Latitude:** 33°30'51.35"N
- **Longitude:** 73°14'33.78"E

North	Open plot
South	Building
East	Road
West	Road



Figure 5-1: Location of the project

5.4 GOVERNMENT APPROVALS

Licensing and registration with the **Drug Regulatory Authority of Pakistan (DRAP)** for pharmaceutical manufacturing is attached as **Annexure A**.

5.5 LAND USE ON THE SITE

The proposed site for IVD Medical Devices Manufacturing Facility by APEX Biotechnology is located at Plot no. 8, central road, Rawat, Rawalpindi, within RCCI Industrial estate Rawat, that has witnessed progressive commercial and industrial development in recent years. The land is currently categorized as industrial/commercial use, making it suitable for establishing a pharmaceutical manufacturing facility. The surrounding land use includes a mix of small-scale industries, warehouses, and commercial outlets, with limited residential settlements at a safe distance.

5.6 ROAD ACCESS

The proposed IVD Medical Devices Manufacturing Facility by Apex Biotechnology is located at Plot No. 8, Central Road, RCCI Industrial Estate, Rawat, Rawalpindi. The site enjoys excellent road connectivity as the RCCI Industrial Estate is directly accessible from the N-5 National Highway (GT Road), which connects Rawalpindi with Lahore and Islamabad. From the GT Road, the site can be approached via the main entrance of the Industrial Estate, leading directly to Central Road, where the plot is situated. The estate has a well-developed internal road network, ensuring smooth access for transportation of raw materials, finished goods, and workforce movement. Additionally, the proximity to Islamabad Expressway and Motorway M-2 enhances regional and national connectivity.

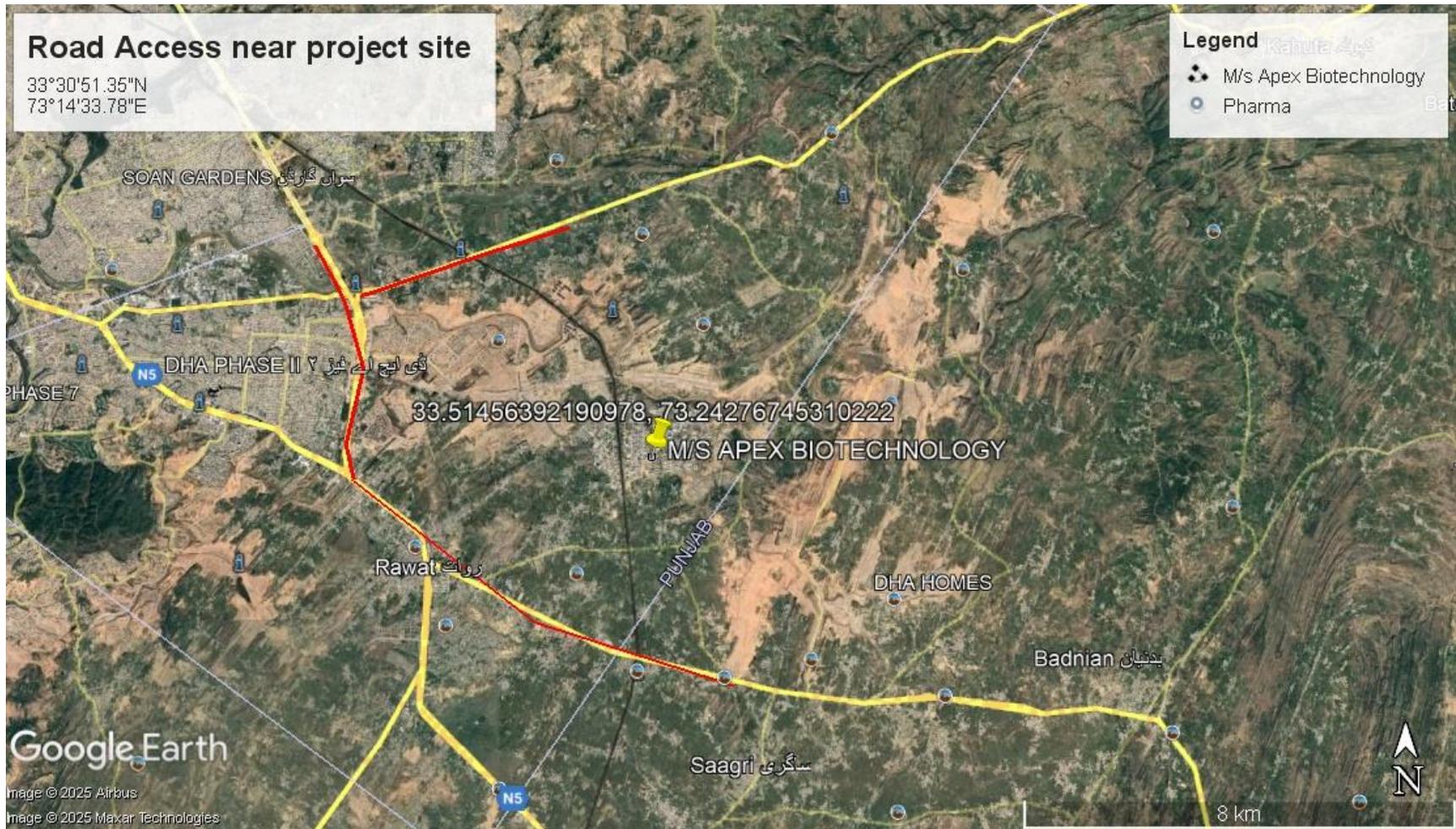


Figure 5-2: Road Access Near the project site

5.7 Vegetation Features Of The Site

The proposed project site of APEX Biotechnology IVD Medical Devices Manufacturing Facility is located at Plot No. 8, Central Road, RCCI Industrial Estate, Rawat, Rawalpindi. The total project area is 2 kanal, situated within a fully developed industrial estate. As the land has already been designated for industrial purposes, it contains minimal natural vegetation. The site is largely barren, with only small patches of grasses and a few scattered shrubs observed. No agricultural activity is carried out within the premises. There are no ecologically significant plant species, natural habitats, or forested areas at the project site. The nearest vegetation is limited to roadside plantations and ornamental trees maintained along internal roads of the RCCI Industrial Estate, as well as in surrounding plots. Therefore, the construction and operation of the proposed facility are not expected to cause any significant adverse impacts on natural vegetation or biodiversity. With proper dust suppression during construction and landscaping measures within the facility, the project can maintain an environmentally responsible footprint.

5.8 SCHEDULE OF IMPLEMENTATION

The outlined project implementation schedule is intended to be followed, contingent upon smooth execution as per the plan and the absence of significant obstacles. The implementation stages of the project activity include:

1st Stage

This stage comprises the following tasks:

- Topographic survey, soil testing, and geotechnical investigations.
- Finalization of the architectural design and layout plan of the pharmaceutical facility.
- Approval of building plan and necessary regulatory clearances.

2nd Stage

This stage comprises the following tasks:

- Ground excavation and foundation laying.
- Civil construction of production blocks, laboratories, and storage areas.
- Installation of utility networks (electricity, gas, and water supply).
- Construction of wastewater management and drainage systems.

3rd Stage

This stage comprises the following tasks:

- Installation of production machinery.
- Installation of HVAC systems and controlled environment areas
- Establishment of in-house laboratories.
- Completion of internal finishing, electrical, and mechanical works

4th Stage

This stage comprises the following tasks:

- Commissioning of machinery and utility systems.
- Trial production runs under supervision of technical experts.
- Training of operational staff on GMP compliance and safety standards.
- Validation and qualification of production processes.

5th Stage

The last stage will be:

- Commencement of full-scale commercial pharmaceutical production.
- Routine monitoring and compliance with DRAP and Punjab-EPA requirements.

5.9 DESCRIPTION OF THE PROJECT

The proposed project involves the establishment of a modern IVD medical devices and diagnostic reagents manufacturing facility by APEX Biotechnology at Plot No. 8, Central Road, RCCI Industrial Estate, Rawat, Rawalpindi, covering a total area of 2 kanal. The project is aimed at creating a fully compliant and state-of-the-art facility for the local production of diagnostic kits and reagents in line with national and international standards. The facility will comprise specialized production sections, including mixing vessels of various capacities (20 L, 5 L, 1 L) for reagent preparation, semi-automated filling and sealing machines, and a carton packaging line for finished products. To support smooth and uninterrupted operations, the project also includes dedicated storage facilities for raw materials, chemical reagents, packaging supplies, and finished goods. Comprehensive quality assurance and regulatory compliance will be ensured through the establishment of in-house Quality Control (QC), Microbiology, and Stability Testing laboratories, fully aligned with Good Manufacturing Practices (GMP) and Drug Regulatory Authority of Pakistan (DRAP) guidelines. The facility will be constructed using a combination of Reinforced Cement Concrete (RCC) and Pre-Engineered Building (PEB) designs to ensure durability, operational efficiency, and compliance with environmental and safety requirements. With a total project investment of approximately PKR 100 million, the development qualifies as a medium-scale industrial project. Once completed, the project will contribute significantly to the healthcare and biotechnology sector by enhancing local capacity for high-quality diagnostic products, reducing reliance on imports, generating skilled employment, and supporting sustainable industrial growth in the region.

5.10 Project components

The proposed project by APEX Biotechnology is focused on the manufacturing and assembling of IVD (In-Vitro Diagnostic) medical reagents. These reagents are prepared using buffer systems, surfactants, salts, stabilizers, and preservatives to create diagnostic solutions used in medical laboratories.

5.10.1 Raw Material Management

- Raw materials such as Triton X-100, Nonidet-40, Sodium Lauryl Sulphate, Quaternary Ammonium Compounds, Buffer salts (Phosphate, HEPES, Tris), Sodium Azide/ProClin,

Sodium Chloride, Potassium Chloride, Glycine, Sodium Sulfate, Polyethylene Glycol are procured from certified suppliers.

- Materials are checked against Certificate of Analysis (CoA) and stored in segregated areas:
 - Hazardous chemicals (e.g., Sodium Azide, ProClin) → chemical storage with ventilation & spill control.
 - Salts, buffers, and surfactants → controlled dry/cool storage.

Table 5-1: List Of Machinery

Category	Raw Material	Purpose / Function in IVD Reagents
Surfactants / Detergents	Triton X-100	Used to break open (lyse) cells and solubilize proteins.
	Nonidet-40	Mild detergent for protein extraction and membrane disruption.
	Sodium Lauryl Sulphate (SLS)	Strong detergent for lysis and denaturation of proteins.
Preservatives / Antimicrobials	Quaternary Ammonium Compound	Prevents microbial growth in reagent solutions.
	Sodium Azide	Broad-spectrum preservative; prevents bacterial contamination.
	ProClin	Stabilizer and preservative for long-term reagent storage.
Buffer Salts	Phosphate Buffer Salts	Maintains pH stability in diagnostic tests.
	HEPES Buffer Salts	Provides stable buffering for biological assays.
	Tris Buffer Salts	Common buffer to maintain pH in enzymatic reactions.
Inorganic Salts	Potassium Chloride (KCl)	Maintains ionic strength and osmotic balance.
	Sodium Chloride (NaCl)	Provides ionic strength; mimics physiological conditions.
	Sodium Sulfate	Used in precipitation and stabilization processes.
Stabilizers / Additives	Glycine	Stabilizer for proteins and enzymes; prevents degradation.
	Polyethylene Glycol (PEG)	Enhances reagent stability and solubility of proteins.

5.10.2 Solution Preparation / Mixing

- Raw materials are weighed according to standard formulations (batch sheets).
- Mixing is carried out in stainless steel or glass reactors/mixers (capacities: 1L, 5L, 20L) depending on production scale.
- Steps include:
 - Dissolving buffer salts (Phosphate, HEPES, Tris) in purified water.
 - Adding surfactants (Triton X-100, Nonidet-40, Sodium Lauryl Sulphate) for stability and solubility.
 - Adding stabilizers (Polyethylene Glycol, Glycine) to improve reagent shelf life.

- Adding preservatives (Sodium Azide, ProClin) to prevent microbial contamination.

5.10.3 Filtration & Sterilization

- Prepared solutions are filtered through membrane filters (0.22 µm) to remove particulates and microbes.
- Some reagents may be sterilized via autoclaving depending on product requirements.

5.10.4 Quality Control (QC)

- QC and Microbiology labs conduct tests on each batch:
 - **Physicochemical tests:** pH, osmolarity, conductivity.
 - **Sterility testing** for microbial contamination.
 - **Stability testing** under different temperatures.
 - **Batch validation** to meet ISO 13485 and cGMP standards.

5.10.5 Filling & Packaging

- Approved batches are transferred to clean filling lines.
- Filling is done into bottles, vials, or kit containers.
- Labels with batch number, expiry date, and storage instructions are applied.
- Automatic carton packing machine packs the final products into cartons for shipment.

5.10.6 Storage & Distribution

- Finished goods are stored in controlled-temperature warehouses (15–25°C).
- Products are distributed to hospitals, diagnostic labs, and research facilities

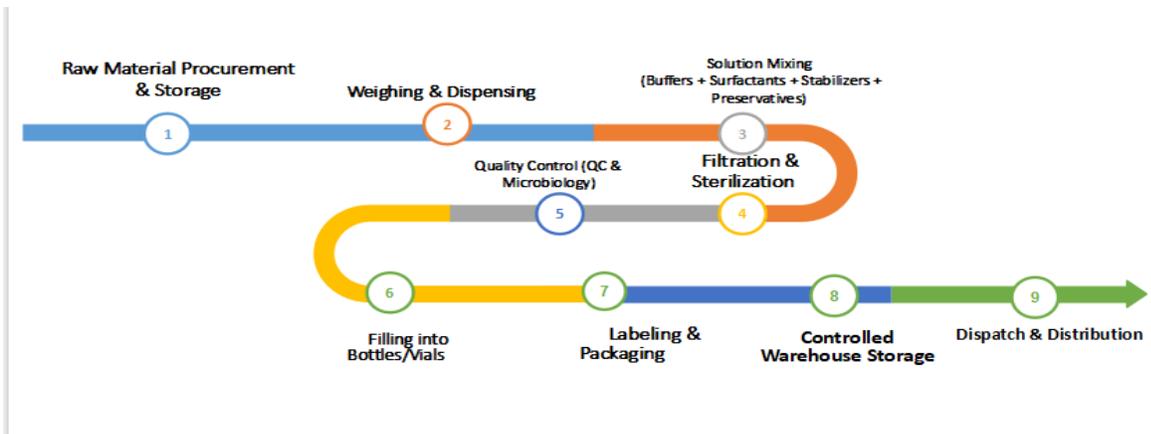


Figure 5-3: process Flow Diagram

APEX Biotechnology		APEX Biotechnology List of RAW Material (Active)				
S/N	Raw Material Name	Type	Lot Number	Supplier	Receipt Date	Expiry Date
1	Iriton X-100	Active				
2	Nonidet-40	Active				
3	Quaternary Ammonium Compound	Active				
4	Sodium Lauryl Sulphate	Active				
5	Phosphate Buffer Salts	Active				
6	HEPES Buffer Salts	Active				
7	Iris Buffer Salts	Active				
8	Sodium Azide, (ProClin)	Active				
9	Potassium Chloride	Active				
10	Sodium Chloride	Active				
11	Sodium Sulfate	Active				
12	Glycine	Active				
13	Polyethylene Glycol	Active				

Figure 5-4: List of Raw Materials by APEX Biotechnology

5.11 Project Capacity

The APEX Biotechnology facility is designed to manufacture diagnostic kits with an estimated capacity of 2.7–5.5 million kits annually under single-shift operation. With two shifts, production can reach up to 11 million kits per year, ensuring a reliable local supply of high-quality diagnostic products.

5.12 Electricity

IESCO will be the main source of electricity for this pharmaceutical unit. Stand-by generator will provide electricity for this Unit in load-shedding Conditions.

5.13 Water supply

The water supply for the proposed project will primarily be provided by the RCCI Industrial Estate management, which ensures availability of utilities such as electricity, water, and sewerage for all industrial units within the estate. In case of additional demand, supplementary water will be arranged through a dedicated tube well or municipal water connection (WASA Rawalpindi), ensuring an uninterrupted and reliable supply for both domestic and industrial needs of the facility.

5.14 Wastewater

For APEX Biotechnology (IVD reagents facility at RCCI Industrial Estate, Rawat, Rawalpindi), wastewater generation will be very limited, since the unit is not a bulk manufacturing plant but a formulation and mixing facility for diagnostic reagents.

Sources of Wastewater

- **Process Wastewater**
 - Small quantities from washing/mixing tanks, cleaning of glassware, and laboratory work.
 - Will mostly contain diluted buffer salts, detergents, and preservatives (all in very low concentration).
- **Domestic Wastewater**
 - Generated from toilets, handwashing, and canteen activities of staff.
 - Similar to normal municipal sewage.
- **Utility Wastewater**
 - From HVAC drain water, boiler blowdown, or RO plant reject (if water purification system is installed).

Estimated Wastewater Quantities

- **Process wastewater:** 1–2 m³/day (small, due to batch reagent preparation).
- **Domestic wastewater:** ~25–30 liters per person per day × estimated staff (e.g., 40–50 staff → 1.5 m³/day).
- **Utility wastewater:** ~0.5–1.0 m³/day.
- **Total Estimated Wastewater = 3–5 m³/day** (very low compared to large pharma plants).

Disposal & Management

- **Process wastewater** will be **neutralized/diluted** and passed through a **small Effluent Treatment Plant (ETP)** within the premises before discharge.
- **Domestic wastewater** will be sent to the **RCCI Industrial Estate sewerage system**, which connects to municipal treatment/disposal.
- **Zero discharge of untreated effluent** will be ensured.

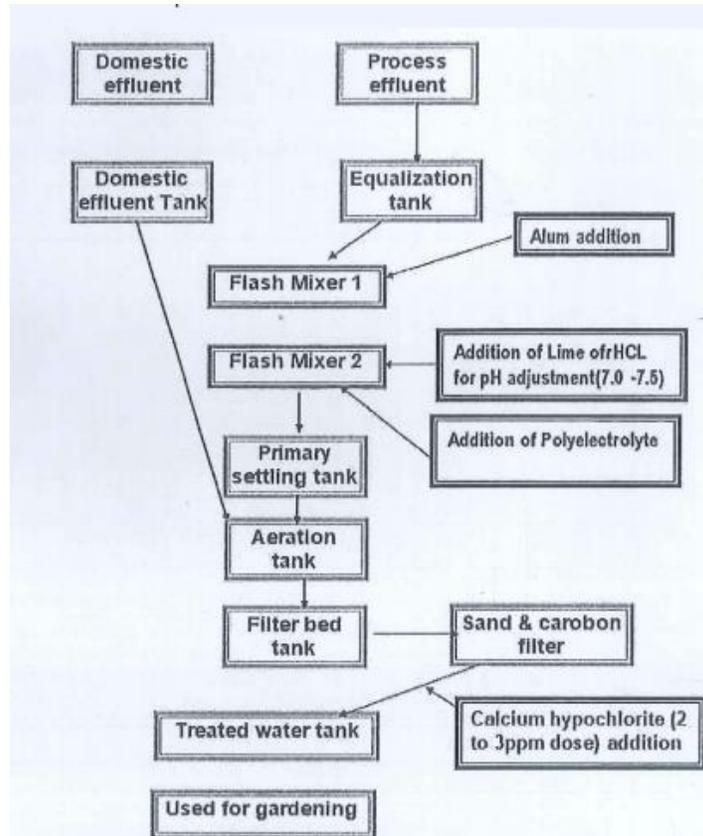


Figure 5-5: Process Flow diagram of Effluent Treatment plant

5.15 Air Emissions

Air emissions from the proposed project will be minimal and localized. The primary sources include standby diesel generators, HVAC systems, and laboratory fume hoods. Emissions will consist mainly of CO₂, NO_x, SO₂, and negligible volatile compounds. All laboratory operations will be conducted under fume hoods equipped with filters, and exhaust air from cleanrooms will be HEPA-filtered to ensure no release of hazardous pollutants. Generator emissions will comply with Punjab Environmental Quality Standards (PEQS) through the installation of adequate stack heights and regular maintenance. Given the mixing-based nature of operations, no significant adverse impacts on ambient air quality are anticipated.

5.16 Noise

Noise emissions from the proposed project will mainly originate from the standby generator, HVAC systems, mixing/packaging machinery, and vehicular movement. Noise levels inside the production hall are expected to remain within 65–75 dB(A), while boundary levels will remain within the permissible limits of Punjab Environmental Quality Standards (PEQS). With mitigation measures such as acoustic enclosures for generators, proper maintenance of machinery, provision of PPE to workers, and development of green buffers, no significant noise-related impacts are anticipated.

5.17 Solid waste

Solid waste from the proposed project will include general office and domestic waste, recyclable packaging material, non-hazardous production residues, and small quantities of hazardous/biomedical waste. The total solid waste generation is estimated at 60–80 kg/day. Waste will be segregated at source, with recyclables handed to licensed vendors, general waste collected by RCCI municipal contractors.. With proper segregation, storage, and disposal practices, no significant environmental impacts are anticipated.

5.18 Area

Total area of plot is 2 kanal.

5.19 Cost of the project

The total cost of the project is 100 Million. The cost Breakup is given as follows:

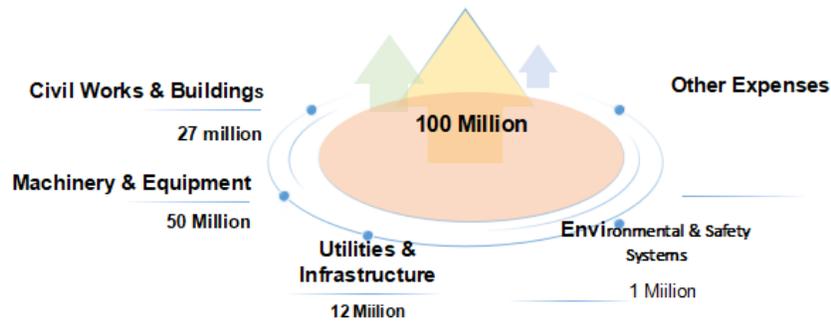


Figure 5-6: cost breakdown of the project

6 DESCRIPTION OF THE ENVIRONMENT

6.1 Introduction

This chapter describes the baseline conditions, which cover the existing physical, ecological, and socio-economic environment of the Study Area. Information on these aspects has been derived from the desk study of available data, field visits to the project area as well as information obtained through visits to the Government departments and other agencies namely Irrigation Department, Meteorological Department, Forest offices and prevailing environmental laws and environmental quality standards etc.

6.2 Desk Studies

Project design data was collected from proponents. This data included the available documents, drawings, reports, etc related to the proposed project. The experts conducted a detailed desk study of the above available data before the field visit. Salient features of the Project were thoroughly reviewed to assess their environmental implications. The documents which were consulted and departments visited are Project Head Office, Project Site, Irrigation Department, Meteorological Department, Forest offices and other related officials.

6.3 Site Visits

A team of experts visited the proposed site to collect baseline environmental data for ambient air, noise levels, drinking water and waste water sampling, public consultation, baseline ecological environment data etc.

After the survey of the project area the environmental data regarding physical, ecological and socioeconomic aspects were collected for carrying out environmental assessment. Secondary data were also collected from various sources mainly studies carried out by project proponents and reports of other line Departments. A social survey of the proposed area was carried in which people living around the proposed unit site were interviewed to ascertain their views about the project commissioning and operational activities to perceive the impacts on the natural and socioeconomic environment around the proposed project site. This included information on land, surface water, groundwater, air, vegetation, animals and human.

6.4 PHYSICAL ENVIRONMENT

Rawalpindi is a prominent city in Punjab province, Pakistan, located immediately south of the federal capital, Islamabad. Together, the two cities form the Islamabad-Rawalpindi metropolitan area, a key political, economic, and strategic region in the country. Rawalpindi serves as the administrative centre of Rawalpindi District and is well-connected through national highways, motorways, and the Islamabad International Airport, making it a vital transit and commercial hub.

The city's origins trace back to ancient times, with archaeological evidence linking it to the Gandhara civilization. The area was historically known as "Ganjipur" and was later settled by the Rawal tribe, from whom the modern name "Rawalpindi" is derived. It

remained a modest settlement until the early 19th century, when it gained importance under Sikh rule.

Rawalpindi's transformation began during the British colonial era when it was established as a major military garrison in 1851. Its strategic location made it the headquarters of the British Northern Command and later a key military centre for Pakistan after independence in 1947. In the 1960s, it served as the temporary capital of Pakistan during the construction of Islamabad.

Today, Rawalpindi is a vibrant urban centre with a mix of colonial heritage, traditional markets, modern infrastructure, and expanding residential and industrial zones. It continues to play a central role in national defence, trade, and regional development, reflecting both its historical legacy and future potential

6.4.1 Topography

Rawalpindi district is in the north of the Punjab province. The highest elevation is 9,210 ft. close to Dunga Gali and in the south it is as low as 1,100 feet. It lies on the Potwar Plateau 9 miles (14 km) southwest of Islamabad, the national capital. The district has an area of 5,286 sq. km. (2,041 sq. mi). Originally, its area was 6,192 km² (2,391 sq. mi) until the 1960s when Islamabad Capital Territory was carved out of the district, giving away an area of 906 sq. km. (350 sq mi). It is situated on the southern slopes of the north-western extremities of the Himalayas, including large mountain tracts with rich valleys traversed by mountain and rivers. The chief rivers are the Indus and the Jhelum, it is noted for its milder climate and abundant rainfall due to its proximity to the foothills.

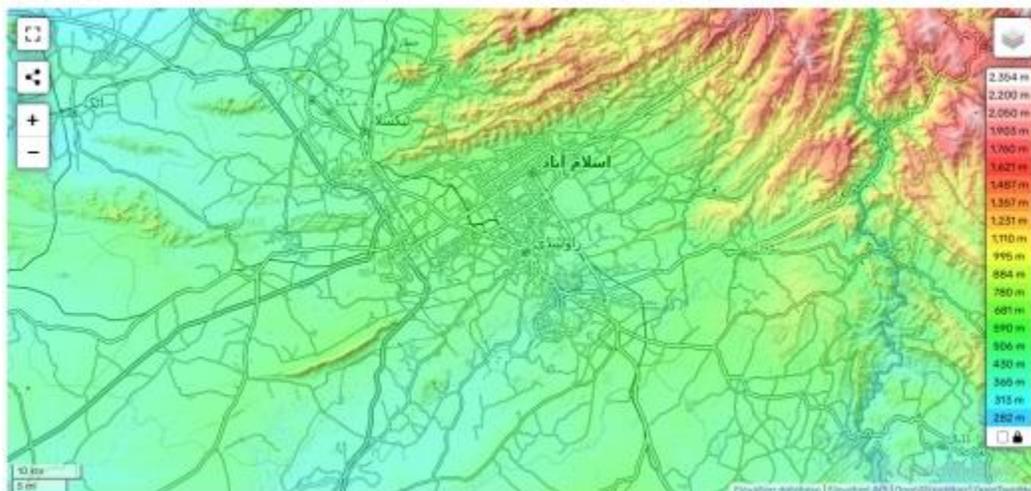


Figure 6-1: Topographic map of Rawalpindi

6.4.2 Soils

The soils of Rawalpindi are primarily derived from the weathering of the Pothohar Plateau's parent rock materials, resulting in a diverse soil profile. The region predominantly features loamy and clayey soils, which are fertile and suitable for agriculture, especially in the peripheral rural areas. These soils often exhibit good water retention properties but can become compact and less permeable, affecting drainage. In some areas, especially where urban development has intensified, soil degradation and erosion are evident due to construction activities and deforestation. The presence of alluvial soils along the streams and nullahs adds to the diversity, providing a mix of fertile grounds for cultivation and areas prone to seasonal waterlogging. Overall, the soils of Rawalpindi support a range of vegetation, from agricultural crops to urban greenery, contributing to the city's mixed land use.

6.4.3 Climate and Meteorology

Rawalpindi has a humid subtropical climate with hot summers, a defined monsoon season, and short, mild winters. Summers, from May to September, are long and intense, with June being the hottest month and temperatures often exceeding **40°C**. The monsoon season (July–September) brings heavy rainfall, occasionally causing urban flooding.

Winters (December–February) are mild, with temperatures ranging between **5°C and 18°C**. The city receives an average annual rainfall of about **1,346.8 mm**, mostly during the monsoon. Rawalpindi also experiences the highest number of thunderstorms in Punjab, averaging nearly **98 per year**, especially in August. Its proximity to the Himalayas contributes to sudden weather changes throughout the year.

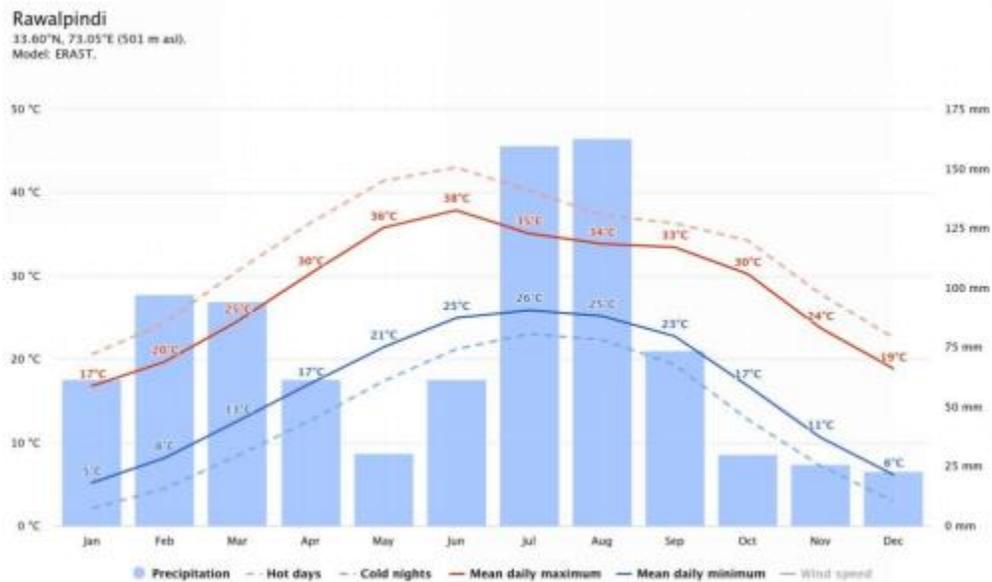


Figure 6-2: Average temperature and precipitation of Rawalpindi

Rawalpindi experiences extreme seasonal variation in monthly rainfall. Rain falls throughout the year in Rawalpindi. The month with the most rain in Rawalpindi is July, with an average rainfall of 6.7 inches. The month with the least rain in Rawalpindi is November, with an average rainfall of 0.5 inches.

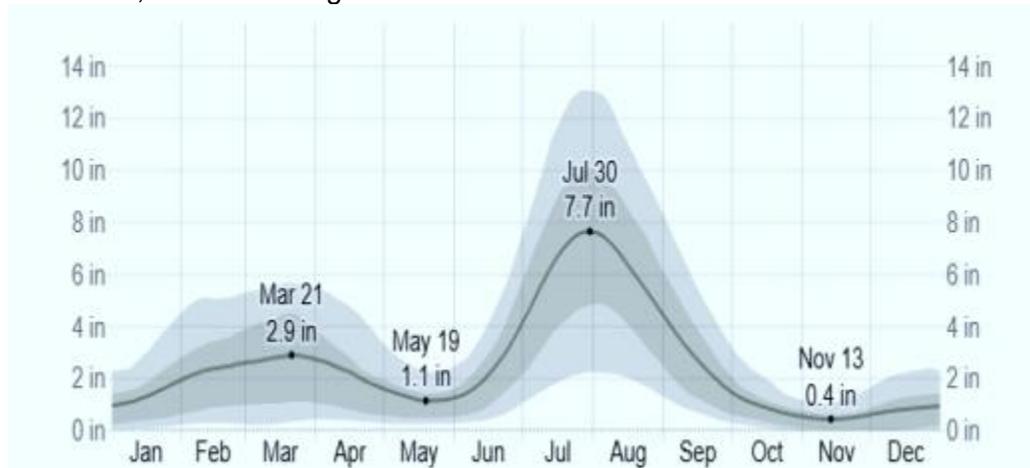


Figure 6-3: Average monthly rainfall in Rawalpindi

6.4.4 SURFACE AND GROUND WATER

Surface Water

Rawalpindi's primary surface water source is the Rawal Dam, which supplies water to both Rawalpindi and Islamabad. Other significant surface water bodies include the Korang River, Soan River, and several seasonal streams (locally called *nullahs*), such as Leh Nullah. These are prone to pollution from domestic and industrial effluents, especially during the monsoon.

Groundwater

Groundwater is extensively used through a network of tube wells, particularly in urban and peri-urban areas. The aquifer is mainly unconfined and replenished through rainfall infiltration and seepage from rivers and canals. However, over-extraction has led to a decline in groundwater levels, particularly in central Rawalpindi, with water tables dropping by approximately 1–2 meters annually in some locations.

Water Quality

Both surface and groundwater sources face contamination risks due to urban runoff, industrial discharges, and poor sanitation infrastructure. Common contaminants include coliform bacteria, nitrates, and heavy metals, especially near densely populated or industrial zones.



Figure 6-4: Rawal Dam

6.4.5 Seismology

The district belongs to Zone 3 of the Seismic Zone Map of Pakistan. This means moderate to severe damage to property due to earthquakes. The region is part of the tectonically active Himalayan zone and experiences **frequent low to moderate earthquakes** (Magnitude 3–5), with rare stronger events.

The **2005 Kashmir earthquake** caused noticeable tremors in Rawalpindi, underlining its vulnerability. Construction in the area must follow **earthquake-resistant design standards** as per the **Building Code of Pakistan (2007)**.

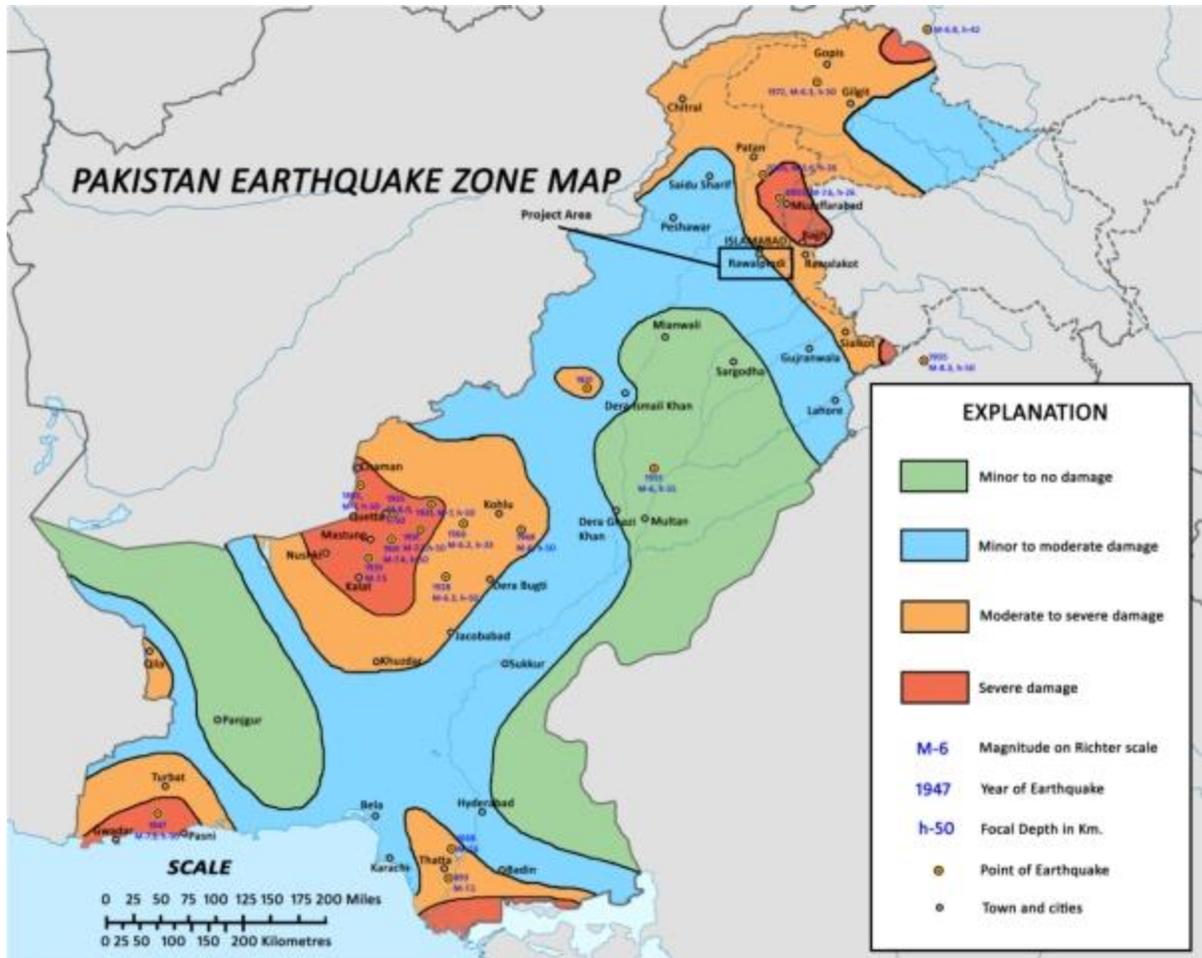


Figure 6-5: Seismic zones map of Pakistan

6.5 ECOLOGICAL RESOURCES

Rawalpindi boasts a range of ecological resources that contribute to its environmental richness and biodiversity. The Margalla Hills National Park, located to the north, is a prominent ecological asset, featuring diverse flora and fauna, including several endangered species. This park provides a vital green lung for the region, supporting various ecosystems from dense forests to scrublands. The Rawal Lake and its surrounding areas serve as important habitats for migratory birds, adding to the avian diversity and providing recreational spaces for residents.

Agricultural lands on the outskirts of the city are another crucial ecological resource, supporting crops, orchards, and pastoral activities that contribute to the local economy. Urban green spaces, parks, and gardens within Rawalpindi offer pockets of biodiversity amidst the urban sprawl, helping to mitigate urban heat island effects and providing recreational areas for the populace. Efforts to preserve and enhance these ecological

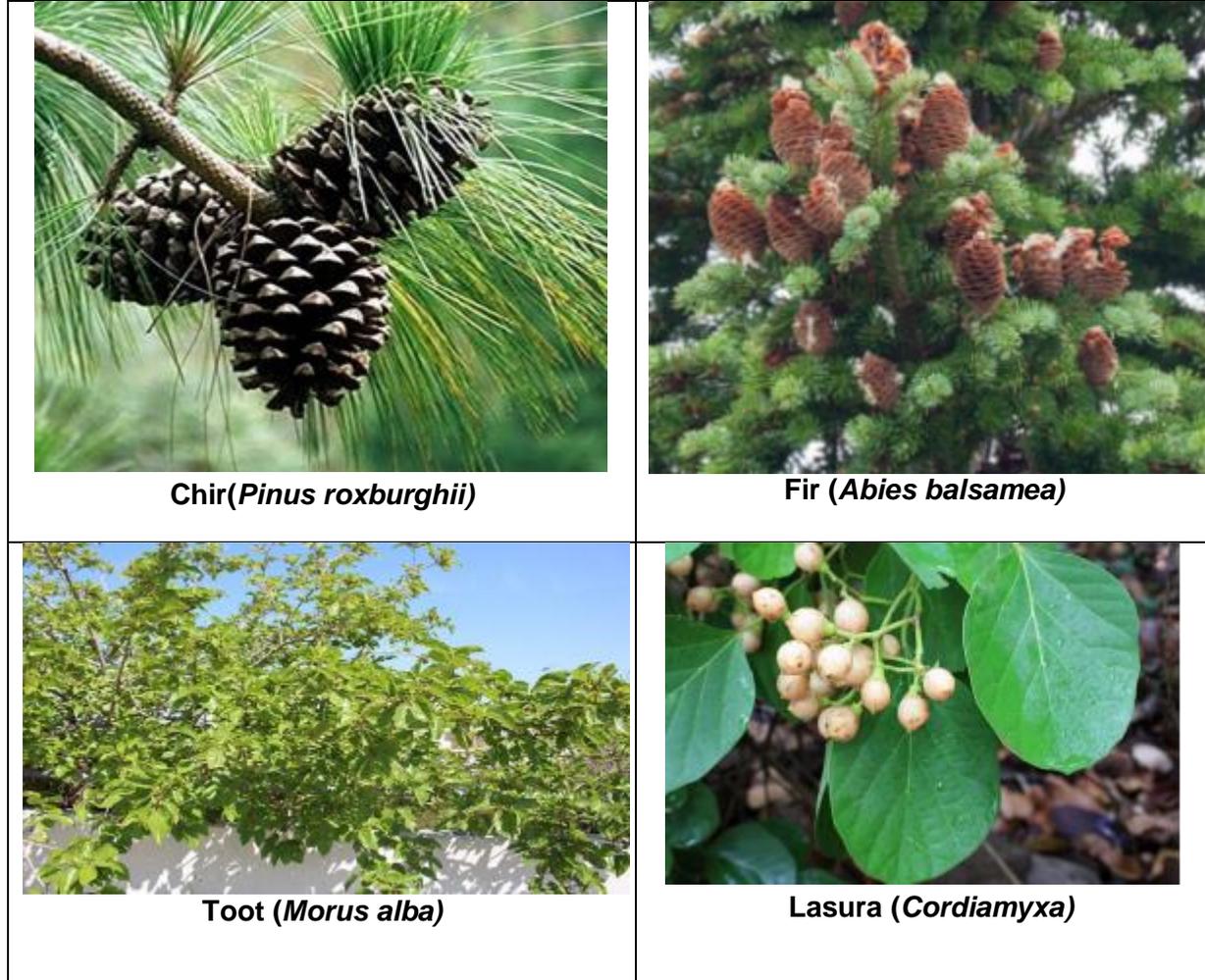
resources are essential for maintaining environmental balance and ensuring sustainable development in the region. Challenges such as urbanization, pollution, and deforestation pose threats to these resources, necessitating proactive conservation and management strategies.

6.5.1 Flora

The flora of Rawalpindi is quite diverse, thanks to its location at the foothills of the Himalayas. Some of the most common trees found in Rawalpindi include

Table 6-1: Flora of the project area

Sr. No.	Common Name	Scientific Name
1.	Shisham	<i>Dalbergia sissoo</i>
2.	Keekar	<i>Acacia arabica</i>
3.	Siris	<i>Albizzia lebbeck</i>
4.	Ber	<i>Ziziphus jujuba</i>
5.	Guava	<i>Psidium guajava</i>
6.	Citrus	<i>Citrus spp.</i>
7.	chir	<i>Pinus roxburghii</i>
8.	Fir	<i>Abies balsamea</i>
9.	Biar	<i>Pinus excels</i>
10.	Toot	<i>Morus alba</i>
11.	Lasura	<i>Cordiamyxa</i>



Chir (*Pinus roxburghii*)

Fir (*Abies balsamea*)

Toot (*Morus alba*)

Lasura (*Cordia myxa*)

Figure 6-6: Flora of the project area

6.5.2 Fauna

Table 6-2: Fauna of the project area

Mammals	
Indian Pangolin	<i>Manis crassicaudata</i>
Indian Hare	<i>Lepus nigricollis</i>
Red Fox	<i>Vulpes vulpes</i>
Indian Grey Mongoose	<i>Herpestes edwardsii</i>
Wild Boar	<i>Sus scrofa</i>
Rhesus Macaque	<i>Macaca mulatta</i>

Indian Crested Porcupine	<i>Hystrix indica</i>
Small Indian Civet	<i>Viverricula indica</i>
Birds	
Indian Peafowl	<i>Pavo cristatus</i>
White-throated Kingfisher	<i>Halcyon smyrnensis</i>
Common Myna	<i>Acridotheres tristis</i>
Black Kite	<i>Milvus migrans</i>
Indian Roller	<i>Coracias benghalensis</i>
House Sparrow	<i>Passer domesticus</i>
Rock Pigeon	<i>Columba livia</i>
Greater Coucal	<i>Centropus sinensis</i>
Barn Owl	<i>Tyto alba</i>
Reptiles	
Indian Cobra	<i>Naja naja</i>
Monitor Lizard	<i>Varanus bengalensis</i>
Indian Flapshell Turtle	<i>Lissemys punctata</i>
Indian Star Tortoise	<i>Geochelone elegans</i>
Saw-scaled Viper	<i>Echis carinatus</i>
Amphibians	
Indus Valley Bullfrog	<i>Hoplobatrachus tigerinus</i>
Skittering Frog	<i>Euphlyctis cyanophlyctis</i>
Common Asian Toad	<i>Duttaphrynus melanostictus</i>



Figure 6-7: Fauna of the project area

6.6 SOCIO-ECONOMIC ENVIRONMENT

Rawalpindi has a vibrant and diverse socioeconomic environment shaped by its urban character, strategic location, and strong institutional presence. As one of Punjab's most urbanized districts, with over 70% of its population living in cities, it benefits from a well-developed infrastructure and close economic integration with the federal capital, Islamabad. The district boasts a high literacy rate of over 83%, supported by numerous public and private educational institutions, including universities and technical colleges. Its economy is service-oriented, with a large portion of the workforce engaged in government, education, healthcare, retail, and small-scale enterprises. While agriculture plays a limited role due to urbanization, Rawalpindi hosts several industrial units in sectors like textiles, pharmaceuticals, and food processing. The district has an extensive healthcare system with major hospitals and basic health units serving both urban and rural populations. Despite these strengths, challenges such as youth unemployment, rising living costs, and pressure on urban services persist, calling for focused policy interventions to support inclusive growth and job creation.

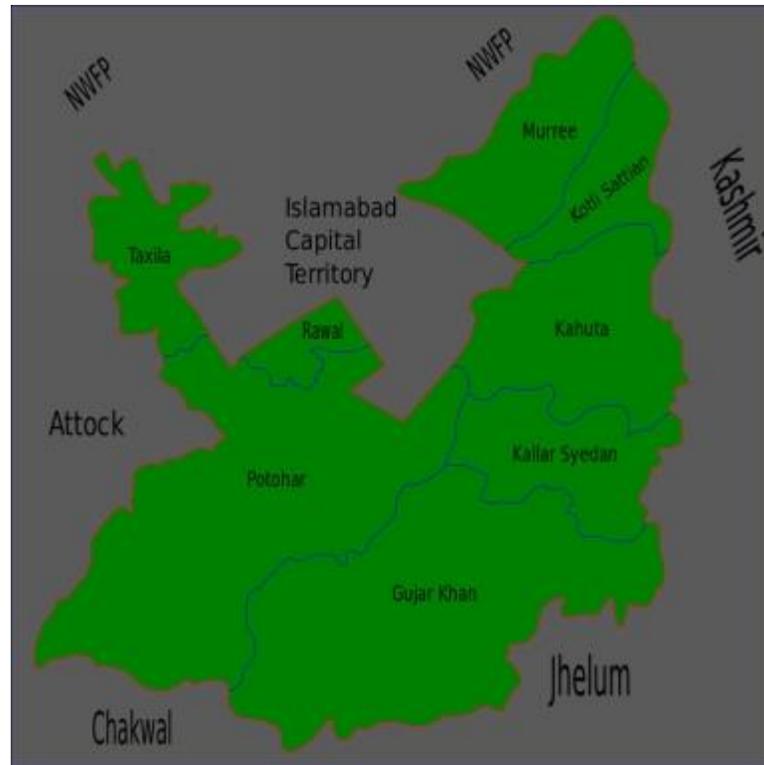


Figure 6-8: Map of Rawalpindi

6.6.1 Population and Demographics

Rawalpindi District, as per the 2023 census, hosts approximately 6.12 million residents across 931,813 households, marking a population increase from 5.40 million in 2017. Around 70% live in urban areas, with 4.21 million in cities and 1.91 million in rural zones. The sex ratio is balanced, with 104 males for every 100 females, and 1,344 transgender individuals recorded.

Total population	6,118,911	
Annual growth (2017–2023)	2.5%	
Gender split	Male	50.7%
	Female	49.3%
Population density	1,039 persons per km ²	
Literacy Rate (age)	Overall 83%	
	Male	90%
	Female	76%

10+)		
Household Size	6.5 persons per house	

6.6.2 Eductaion and Literacy

Rawalpindi District exhibits strong educational indicators compared to national averages. According to the 2023 census, the literacy rate in the district is 83.1%, with male literacy at 87.6% and female literacy at 78.3%. The district has a well-established network of educational institutions, including public and private schools, colleges, and universities. Notable higher education institutions include Pir Mehr Ali Shah Arid Agriculture University, Fatima Jinnah Women University, Rawalpindi Medical University, and branches of national universities such as NUML and Virtual University. In addition to formal education, the district also supports technical and vocational training centers aimed at skill development, particularly for youth. The urban areas, which make up about 70% of the population, benefit from better access to educational resources, while efforts are ongoing to improve literacy and school enrollment in rural areas. The high literacy rate and availability of diverse educational facilities contribute to a relatively skilled and informed population, which is an important factor in the sustainable planning and implementation of development projects.

Details of schools in district are as follows:

Gujar Khan	07
Kahuta	204
Kallar Syedan	201
Kotli Sattian	183
Murree	232
Rawalpindi	483
Taxila	104



Fatima Jinnah Women University



Pir Mehr Ali Shah Arid Agriculture University

Figure 6-9: Notable universities of the area

The district also emphasizes technical and vocational education through institutions such as the Government Technical Training Institute, Punjab Vocational Training Council centers, and TEVTA colleges, which provide skill-based training in trades like electrical work, IT, fashion design, and mechanical technologies.

Despite the overall high literacy rate, rural areas still face disparities in school access, female enrollment, and infrastructure quality. Government initiatives, including school rehabilitation programs, girls' stipend schemes, and enrollment drives, aim to address these gaps. The availability of educated and skilled human resources in Rawalpindi plays a vital role in supporting industrial activity, public administration, and the service sector, and is a positive socio-economic factor for any proposed development interventions in the area.

6.6.3 Health facilities

Rawalpindi offers a comprehensive healthcare ecosystem comprising public, military, and private providers, along with community clinics and outreach programs:

Public Hospitals & Primary Care:

- Benazir Bhutto Hospital (750 beds) and Holy Family Hospital (864 beds) are major teaching hospitals affiliated with Rawalpindi Medical University. The district runs over 98 Basic Health Units (BHUs) and multiple Rural and Tehsil Health Centers. Starting February 2025, seven BHUs have been outsourced and rebranded as "Maryam Nawaz Clinics," offering free basic healthcare and maternal services.
- The Punjab Healthcare Commission (PHC) actively ensures public and private providers meet WHO standards and hold proper licensing.

Military & Specialized Hospitals:

- **Combined Military Hospital (CMH) Rawalpindi**, a 1,200-bed facility, is the largest military hospital offering tertiary care and teaching programs. Some civilians report mixed experiences, including delayed treatment on weekends .
- **Armed Forces Institute of Cardiology (AFIC)**, with 800 beds, provides advanced cardiac care to military and civilian patients
- **Rawalpindi Leprosy Hospital** is the region's oldest specialized facility, offering outpatient/inpatient services under a mission-run model

Private & Semi-Private Sector:

- Numerous private hospitals such as **Bahria International, Al-Khidmat Razi, Bilal Hospital, Mega Medical Complex**, and others are empaneled under the Sehat Card program for subsidized care

Teaching & Capacity:

- **Rawalpindi Medical University** oversees medical training at Benazir Bhutto, Holy Family, and DHQ hospitals, with around 3,000 beds dedicated to teaching and clinical education

Access & Quality Assurance:

- Only 19% of primary care facilities provide access within a 5 km radius, indicating potential gaps in geographic coverage
- The PHC's recent regulatory drive aims to standardize care quality, closing unlicensed facilities and enforcing compliance.

6.6.4 Economic activity

Rawalpindi is one of the more important cities of Pakistan. After the weakening of the Mughal Dynasty, Sikhs gained power in this area and invited nearby traders to live in the city. The city, thus, became a hub of trade due to its strategic location, connecting Punjab and Kashmir.

Agriculture with its Allied Livestock Breeding, Fishing	8.4%
Manufacture	5.3%
Construction	10.3%
Wholesale/ Retail, Hotel/ Restaurant	11.7%
Transport, Storage, Communication	2.8%
Community, Social & Personal	45.3%

Services	
Activities Not Adequately Defined	15.3%
Others	0.9

Overall, Rawalpindi's economy is service-led, with the secondary sector providing significant but modest industrial employment. Agriculture remains vital for rural income, while construction and real estate growth support urban expansion. These dynamics reflect a balanced socio-economic environment shaped by urbanization, infrastructure development, and proximity to the capital city.

6.6.5 Religion

Muslims	97.7%
Christians	2.1%
Hindus	Negligible %
Ahmadis	0.14%
Schedule Castes	Negligible %
Others	Negligible %

6.6.6 Language

Urdu	1,029,015
Punjabi	3,596,866
Sindhi	17,362
Pushto	630,908
Balochi	3,911
Saraiki	40,031
Hindko	236,986
Brahvi	370
Mewati	522
Kohistani	10,921
Other Language	491,648

6.6.7 Site suitability

The proposed project site, Plot No. 8, Central Road, RCCI Industrial Estate, Rawat, Rawalpindi, is highly suitable for establishing the IVD medical devices manufacturing facility. The land is located within a designated industrial estate, with no significant ecological habitats or protected areas nearby, ensuring negligible environmental sensitivity. The site benefits from excellent infrastructure, including road access via Islamabad Expressway and GT Road, along with availability of utilities such as electricity, water supply, natural gas, and telecommunication. Being part of an established industrial zone, the project aligns well with surrounding land use and ensures efficient logistics and operations. Socio-economically, the project will create employment, support industrial growth, and contribute to healthcare development. Preliminary consultations indicate community support, making this location optimal for sustainable and compliant medical device manufacturing.

7 SCREENING OF POTENTIAL ENVIRONMENTAL IMPACTS & MITIGATION MEASURES

7.1 General

The importance of impact assessment in EIA cannot be overstated, as it serves as a fundamental tool for evaluating and understanding the potential effects of a proposed project on the environment. Impact assessment systematically identifies, predicts, and evaluates the anticipated positive and negative consequences of a project, considering various environmental aspects such as air and water quality, biodiversity, soil health, and community well-being. This process is pivotal in informed decision-making, enabling stakeholders to assess the trade-offs and make choices that balance development with environmental conservation. The impact assessment phase provides a comprehensive understanding of the project's potential impacts, allowing for the development of effective mitigation measures and strategies to minimize or eliminate adverse effects. Additionally, it fosters transparency and accountability by providing a basis for public consultation and engagement, ensuring that the concerns and perspectives of affected communities are considered. Overall, impact assessment in EIA is essential for promoting sustainable development practices, preventing environmental degradation, and fostering responsible and informed decision-making in the planning and execution of projects.

7.2 Project Area of Influence

Before commencing the environmental analysis of the proposed pharmaceutical project, it is essential to define the specific Area of Influence (AoI). While the primary construction and operational activities will remain confined within the project's designated boundaries, there are certain aspects where project-related activities may extend beyond these limits. These include:

- Temporary establishment of construction camps and storage of construction material.
- Transportation and handling of machinery, equipment, and raw materials.
- Movement of labor and associated domestic activities.
- Minor infrastructure requirements such as internal access roads and utility connections.

Environmental impacts have been assessed within the 0.5 km boundary of the proposed pharmaceutical facility. The surrounding area has been considered for identifying potential impacts such as construction-related noise, dust emissions, traffic movement, and socio-economic influence.

Accordingly, the identification of environmental impacts and the recommendation of mitigation measures are limited to this defined Area of Influence.

7.3 Methodology for impact assessment

The methodology for assessing the risk level associated with each potential impact is presented below. Risk has been assessed as the likelihood that the activity will have an effect on the environment as well as the consequence of the effect occurring.

$$\text{Risk} = \text{Likelihood} \times \text{Consequence}$$

Likelihood Scale

Likelihood	Definition	Scale
Certain	Will certainly occur during the activity at a frequency greater than every week if preventative measures are not applied.	5
Likely	Will occur more than once or twice during the activity but less than weekly if preventive measures are not applied.	3
Unlikely	May occur once or twice during the activity if preventive measures are not applied.	2
Rare	Unlikely to occur during the project.	1

Consequence Scale

Consequence	Definition	Score
Catastrophic	The action will cause unprecedented impacts.	5
Major	The action will cause major adverse impacts.	3
Moderate	No or minimal impacts.	2
Minor	No or minimal impacts.	1

Risk Score Table

Likelihood	Consequence			
	Catastrophic	Major	Moderate	Minor
Certain	25	15	10	5
Likely	15	9	6	3
Unlikely	10	6	4	2
Rare	5	3	2	1

Risk: Significant: 15-25

Medium: 6-10

Low: 1-5

Any 'Medium' to 'Significant' risk requires an environmental management measure to manage the potential environmental risk. Judgment will be required concerning the application of an environmental management measure to mitigate low risk situations

7.4 Impacts during design/pre-construction phase

Screening of possible Impacts during Design/Pre- Construction phase

S/No.	Potential Issue	Likelihood	Consequence	Risk Level	Residual Impact
1	Improper facility design not meeting GMP / DRAP standards for IVD manufacturing	Unlikely	Major	Medium	Long Term
2	Incorrect siting near sensitive receptors (residential/schools/hospitals)	Rare	Major	Medium	Long Term
3	Use of substandard construction materials or non-certified equipment	Likely	Moderate	Medium	Long Term
4	Inadequate fire safety & emergency systems in design	Possible	Major	High	Long Term
5	Occupational health & safety risks during site clearing and preparation	Likely	Moderate	Medium	Short Term
6	Community disturbance (dust, noise, traffic) during pre-construction	Likely	Minor	Low	Short Term

1. Improper facility design not meeting GMP / DRAP standards for IVD manufacturing

If the facility design for IVD medical device manufacturing does not comply with GMP and DRAP standards, it can lead to a range of serious consequences. Inadequate layout, poor segregation of processes, or insufficient cleanroom controls may compromise sterility and increase the risk of contamination or cross-contamination, directly affecting the quality and safety of the diagnostic devices. Such lapses could result in regulatory non-compliance, leading to product recalls, delays in licensing, financial penalties, or even suspension of operations by authorities. Improper ventilation and HVAC systems may also expose workers to hazardous chemical reagents and biological agents, creating occupational health and safety risks. Beyond immediate operational concerns, failure to meet international quality standards would harm the credibility and market reputation of the company, limiting both domestic and export opportunities. In the long term, this could reduce stakeholder trust, restrict the facility's role in supporting healthcare systems, and undermine the economic viability of the project.

Mitigation Measure

Following mitigation measures will be implemented

- GMP-Compliant Facility Design: Adopt international cGMP standards for cleanroom classifications, material/personnel flow, and proper segregation of high-risk operations.
- Regulatory Approvals: Engage DRAP during the design and construction phase to ensure facility layouts, utilities, and equipment meet mandatory requirements.
- HVAC & Airflow Controls: Install properly designed Heating, Ventilation, and Air Conditioning (HVAC) systems to maintain controlled environments with HEPA filtration and pressure differentials.
- Validation & Certification: Conduct third-party validation of cleanrooms, utilities, and processes before commissioning; maintain continuous audits and inspections.
- Training & SOPs: Train staff on GMP/DRAP standards and implement strict Standard Operating Procedures (SOPs) for cleaning, disinfection, and material handling.
- Quality Management System (QMS): Establish a robust QMS to ensure continuous monitoring, corrective actions, and compliance with regulatory updates.

2. Incorrect siting near sensitive receptors (residential/schools/hospitals)

If the Apex Biotechnology IVD medical devices manufacturing facility were incorrectly sited near sensitive receptors such as residential areas, schools, or hospitals, it could create multiple adverse impacts. The presence of an industrial unit in close proximity to such receptors would increase the risk of nuisance from construction and operational activities, including noise, vehicular traffic, and dust emissions. Although IVD manufacturing does not involve heavy chemical processing, the handling of reagents, packaging materials, and solid or liquid waste could pose risks of accidental exposure or improper disposal, potentially affecting nearby populations. Sensitive groups such as children, patients, and the elderly could be more vulnerable to even minor disturbances or exposure. Additionally, increased traffic movements for raw material delivery and product distribution could lead to congestion, road safety concerns, and restricted access around schools or hospitals. From a regulatory perspective, siting the facility in or near non-industrial areas would also violate zoning and environmental compliance requirements, potentially causing community opposition and reputational damage to the project. In contrast, the chosen site within RCCI Industrial Estate minimizes these risks, as it is specifically designated for industrial activities and is located away from residential and sensitive receptors, making it a far more suitable and sustainable option.

Mitigation measure

- Conduct site suitability assessment before finalizing location.
- Maintain buffer zones (green belts, boundary walls) between plant and sensitive areas.
- Ensure compliance with zoning regulations and obtain local authority approval.

3. Use of substandard construction materials or non-certified equipment

If substandard construction materials or non-certified equipment are used in the Apex Biotechnology facility, it could compromise structural integrity, cleanroom standards, and operational safety. Poor quality finishes may lead to contamination risks, leakage, or equipment failure, directly affecting product quality and regulatory compliance. This could also increase maintenance costs, operational downtime, and the likelihood of accidents, ultimately damaging the facility's credibility and market acceptance.

Mitigation Measures

Following mitigation measures are recommended

- Procure only certified construction materials and equipment that comply with DRAP, GMP, and international standards.
- Ensure all equipment is sourced from approved vendors with proper quality certifications (e.g., ISO, CE, FDA).
- Conduct third-party quality assurance checks during construction and installation.
- Implement strict procurement and inspection protocols before acceptance of supplies.
- Carry out regular audits and preventive maintenance to ensure long-term compliance and performance.

4. Inadequate fire safety & emergency systems in design

If the Apex Biotechnology facility lacks adequate fire safety and emergency systems in its design, it could lead to severe risks for workers, equipment, and stored chemical reagents. In case of a fire or accidental spill, delayed response or absence of proper systems may result in injuries, property damage, and disruption of operations. It may also cause regulatory non-compliance, legal liabilities, and loss of stakeholder trust, ultimately threatening the sustainability of the project.

Mitigation measures

- Design and install a comprehensive fire detection and suppression system (smoke detectors, sprinklers, fire alarms).
- Ensure compliance with National Fire Safety Codes, DRAP, and international standards.
- Provide fire extinguishers, emergency exits, and clearly marked evacuation routes throughout the facility.
- Conduct regular fire drills and staff training on emergency response procedures.
- Establish an on-site emergency response plan and coordinate with local fire and rescue services.

5. Occupational health & safety risks during site clearing and preparation

During site clearing and preparation for the Apex Biotechnology project, occupational health and safety risks may arise due to dust emissions, noise, debris handling, and the use of heavy machinery. Workers may face exposure to respiratory problems, hearing loss, or physical injuries such as cuts, falls, or accidents with equipment. Inadequate protective measures and lack of training could further increase the risk of workplace incidents, resulting in delays, reduced productivity, and potential non-compliance with labor and safety regulations.

Mitigation Measures

- Provide all workers with appropriate PPE (helmets, gloves, masks, safety shoes, ear protection).
- Implement dust suppression measures (e.g., water sprinkling) and maintain proper housekeeping.
- Conduct safety training and toolbox talks before starting site activities.
- Ensure safe operation of machinery with trained operators and regular maintenance checks.
- Establish first-aid facilities, emergency response plans, and clear evacuation routes on site.
- Restrict unauthorized access to work zones through fencing and warning signage.

6. Community disturbance (dust, noise, traffic) during pre-construction

For the Apex Biotechnology project, community disturbance during pre-construction may arise due to dust emissions from land clearing, excavation, and material handling, which can reduce local air quality and cause discomfort or respiratory irritation to nearby residents. Noise from construction equipment, machinery, and vehicle movement can disturb the peace of the surrounding community, especially if activities occur during early morning or late evening hours. Increased traffic from the transport of construction materials and machinery may lead to congestion, road safety concerns, and inconvenience for local commuters. If not managed properly, these impacts can create temporary nuisance, reduce community acceptance of the project, and negatively affect relationships with stakeholders.

Mitigation measures

Following mitigation measures are suggested:

- Sprinkle water on exposed soil and unpaved surfaces to control dust emissions.
- Cover construction materials and trucks during transportation to prevent dust dispersion.
- Use well-maintained and low-noise machinery; restrict noisy activities to daytime hours only.
- Install temporary noise barriers where sensitive receptors (residences, schools, clinics) are nearby.
- Prepare a traffic management plan to avoid congestion and ensure safe movement of construction vehicles.
- Coordinate with local authorities and inform the community about construction schedules in advance

7.5 Impacts during Construction phase and Mitigation measures Screening of possible Impacts during Construction phase

S/No.	Potential Issue	Likelihood	Consequence	Risk Level	Residual Impact
1	Dust emissions from excavation, material handling, and vehicle movement	Likely	Moderate	Medium	Short Term
2	Noise and vibration from construction machinery and equipment	Likely	Minor	Low	Short Term
3	Improper disposal of construction debris and packaging waste	Possible	Moderate	Medium	Medium Term
4	Accidental spillage of fuels, lubricants, or construction chemicals	Possible	Major	High	Medium Term
5	Increased traffic and congestion from material and equipment transport	Likely	Minor	Low	Short Term

6	Occupational health and safety risks to construction workers	Likely	Major	High	Short Term
7	Disturbance to nearby communities due to dust, noise, and traffic	Possible	Moderate	Medium	Short Term
8	Improper storage of construction materials leading to contamination/fire	Unlikely	Major	Medium	Medium Term
9	Accidental damage to utilities (water, electricity, telecom lines)	Rare	Major	Medium	Short term

1. Dust emissions from excavation, material handling, and vehicle movement

Impact: Dust generated during excavation, handling of raw materials, and movement of heavy vehicles can reduce ambient air quality, cause respiratory discomfort to workers, and affect nearby residents. Continuous exposure may aggravate respiratory illnesses, while dust deposition on vegetation can hinder growth..

Mitigation:

- Regular water sprinkling on unpaved areas and excavation sites.
- Cover all trucks transporting materials.
- Store fine materials under tarpaulins.
- Provide masks and PPE to workers.

2. Noise and vibration from construction machinery and equipment

Impact: Operation of heavy machinery, drilling, and transport vehicles will generate significant noise and vibrations. This may disturb nearby residents and sensitive receptors, cause hearing fatigue for workers, and, in prolonged cases, lead to hearing loss or stress-related issues. Vibrations can also cause minor structural impacts on weak surrounding buildings.

Mitigation Measure:

Following mitigation measures can be implemented

- Use well-maintained and low-noise machinery.
- Restrict high-noise activities to daytime hours.
- Provide ear protection to workers.
- Install temporary noise barriers where needed.

3. Improper disposal of construction debris and packaging waste

Impact: If not managed properly, debris (concrete, soil, packaging, plastics) can block drainage, contaminate land, and create unhygienic conditions. Open dumping may attract rodents and pests, while burning of packaging materials releases harmful emissions into the air.

Mitigation:

Following mitigation measures are suggested:

- Segregate waste (recyclable, reusable, non-recyclable).
- Dispose of waste through an approved municipal/industrial waste contractor.
- Avoid open dumping or burning on site.

4. **Accidental spillage of fuels, lubricants, or construction chemicals**

Impacts: Leaks and spills from machinery or chemical storage areas may contaminate soil and groundwater, posing risks to both human health and the surrounding environment. In addition, spilled fuels are highly flammable, increasing fire and explosion risks if not properly controlled.

Mitigation Measure:

Following mitigation measures are suggested

- Store fuels and lubricants in designated, bunded areas.
- Use drip trays under machinery.
- Train workers in spill response; keep spill kits on site.
- Immediate clean-up of spills with absorbent materials.

5. **Increased traffic and congestion from material and equipment transport**

Impact: The movement of trucks and heavy machinery may increase traffic load on local roads, leading to congestion, delays, and higher accident risks. Communities living along transport routes may experience inconvenience, noise, and reduced road safety.

Mitigation:

- Prepare a traffic management plan with designated routes.
- Schedule deliveries during off-peak hours.
- Place warning signs near entry/exit points.
- Coordinate with local authorities for traffic control if required.

6. **Occupational health and safety risks to construction workers**

Impacts: Workers face risks of injuries from falls, improper equipment handling, and accidents involving heavy machinery. Exposure to dust, noise, and chemicals may also cause respiratory and dermatological problems. Without proper training and PPE, the likelihood of accidents increases significantly.

Mitigation Measure:

- Provide PPE (helmets, gloves, masks, safety shoes).
- Conduct regular safety training and toolbox talks.
- Ensure first aid facilities and emergency response systems on site.
- Supervise workers to enforce safety rules.

7. **Disturbance to nearby communities due to dust, noise, and traffic**

Impact: Communities in the vicinity may face temporary disturbances, including increased dust, high noise levels, and traffic congestion. This can reduce overall living quality, cause stress, and lead to public complaints if not managed effectively..

Mitigation:

- Maintain regular communication with nearby residents.
- Inform the community about construction schedules in advance.
- Implement dust and noise control measures as noted above.
- Restrict heavy vehicle movement in residential streets.

8. Improper storage of construction materials leading to contamination/fire

Construction materials stored in open areas may leach contaminants into soil and water during rainfall. Improper storage of fuels, lubricants, or chemicals increases the risk of accidental fire, while cluttered storage areas may block emergency exits and create unsafe working condition

Mitigation Measure:

- Store materials in designated, labeled areas with fire safety provisions.
- Keep chemicals and fuels in ventilated, bunded storage.
- Prohibit smoking or open flames near storage areas.
- Conduct regular safety inspections.

9. Accidental damage to utilities (water, electricity, telecom lines)

Impact: Excavation or construction activities may accidentally damage underground or overhead utilities. This can cause service interruptions for nearby communities, pose risks of electrocution or flooding, and lead to costly delays in construction due to emergency repairs..

Mitigation:

- Identify and map all utilities before excavation.
- Coordinate with utility providers for safe relocation or protection.
- Mark restricted zones to avoid accidental digging.
- Immediate repair and reporting in case of accidental damage.

7.6 : Impacts during operational Phase

Screening of possible Impacts during Operational Phase

S/No.	Potential Issue	Likelihood	Consequence	Risk Level	Residual Impact
1	Air emissions from generators and HVAC systems	Likely	Moderate	Medium	Long Term
2	Improper treatment/disposal of biomedical/chemical effluents from reagent preparation	Possible	Major	High	Long Term
3	Solid and hazardous waste mismanagement (expired reagents, plastic consumables, packaging waste)	Likely	Major	High	Long Term
4	Cross-contamination between diagnostic kit production areas due to poor controls	Unlikely	Major	Medium	Long Term
5	Noise from continuous operation of HVAC, compressors, and machinery	Possible	Minor	Low	Long Term

6	Occupational health risks to workers (chemical exposure, ergonomic strain, accidental spills)	Likely	Major	High	Long Term
7	Fire hazards from storage of flammable chemicals and reagents	Possible	Major	High	Long Term
8	High energy and water consumption (purified water, HVAC demand) impacting resource sustainability	Likely	Moderate	Medium	Long Term
9	Community complaints due to emissions, noise, or transport activities	Possible	Moderate	Medium	Long Term
10	Non-compliance with GMP, DRAP, or biosafety standards	Rare	Major	Medium	Long Term

1. Air emissions from generators and HVAC systems

- **Impact:** Operation of diesel generators and HVAC exhaust may release pollutants such as NO_x, CO, particulate matter, and greenhouse gases. This can reduce local air quality, contribute to smog, and cause respiratory discomfort to workers and nearby communities. Continuous emissions also add to climate change burden.
- **Mitigation:**
 - a. Use low-sulfur diesel and well-maintained, fuel-efficient generators.
 - b. Install exhaust silencers and catalytic converters where feasible.
 - c. Adopt energy-efficient HVAC systems with regular filter cleaning.
 - d. Monitor stack emissions periodically to ensure compliance with PEQS.

2. Improper treatment/disposal of biomedical/chemical effluents from reagent preparation

- **Impact:** Discharge of untreated liquid waste (biological residues, solvents, cleaning chemicals) can contaminate soil and groundwater, harm aquatic ecosystems, and create public health hazards. Improper effluent management may also lead to regulatory penalties.
- **Mitigation:**
 - Install an Effluent Treatment Plant (ETP) with neutralization and disinfection units.
 - Segregate biomedical and chemical effluents for safe handling.
 - Ensure compliance with hospital/biomedical waste management rules and PEQS.
 - Regular monitoring of treated wastewater before discharge.

3. Solid and hazardous waste mismanagement (expired reagents, plastic consumables, packaging waste)

- **Impact:** Mismanagement of expired reagents, used pipettes, and packaging materials may lead to land contamination, infection risks, and attraction of vermin. Burning plastics can release toxic dioxins, impacting air quality.
- **Mitigation:**
 - Establish a dedicated waste segregation system (hazardous, biomedical, recyclable, general).
 - Partner with licensed hazardous waste disposal contractors.
 - Maintain an on-site waste storage area with impermeable flooring.
 - Promote recycling of paper, plastics, and packaging materials.

4. Cross-contamination between diagnostic kit production areas due to poor controls

- **Impact:** Inadequate segregation of cleanrooms, reagent preparation, and kit assembly areas may lead to contamination of products, compromising diagnostic accuracy and patient safety. This can result in regulatory non-compliance and reputational damage.
- **Mitigation:**
 - Maintain strict zoning with differential air pressure in cleanrooms.
 - Implement SOPs for gowning, entry/exit, and material transfer.
 - Regular microbiological monitoring of controlled areas.
 - Adopt GMP-compliant facility design with physical barriers.

5. Noise from continuous operation of HVAC, compressors, and machinery

- **Impact:** Constant noise can cause occupational stress, hearing discomfort, and reduced productivity of workers. It may also create disturbances for nearby communities if not controlled.
- **Mitigation:**
 - Install noise silencers and acoustic insulation for HVAC and compressors.
 - Maintain machinery regularly to reduce vibrations.
 - Provide PPE (earplugs/earmuffs) to workers in high-noise zones.
 - Restrict operations of noisy equipment to daytime where possible.

6. Occupational health risks to workers (chemical exposure, ergonomic strain, accidental spills)

- **Impact:** Workers may face exposure to hazardous reagents, repetitive strain injuries from manual handling, and risks of chemical burns or skin irritation. Accidental spills can cause localized contamination and health risks.
- **Mitigation:**
 - Provide PPE (gloves, goggles, lab coats, respirators where needed).
 - Train workers on chemical handling, spill response, and ergonomics.
 - Maintain spill kits and emergency showers at critical points.
 - Conduct regular occupational health and safety (OHS) audits.

7. Fire hazards from storage of flammable chemicals and reagents

- **Impact:** Improperly stored solvents, alcohols, or reagents can pose a fire or explosion risk, threatening human life, property, and continuity of operations.
- **Mitigation:**
 - Store flammable chemicals in fire-rated cabinets with proper ventilation.

- Install fire detection, alarms, and suppression systems (sprinklers, extinguishers).
- Conduct regular fire safety drills and staff training.
- Keep emergency exits clear and accessible at all times.

8. High energy and water consumption (purified water, HVAC demand) impacting resource sustainability

- **Impact:** Continuous demand for purified water and HVAC operations may strain local utilities, increase operational costs, and contribute to environmental footprint. Excessive water use may deplete groundwater resources.
- **Mitigation:**
 - Install energy-efficient HVAC and lighting systems.
 - Use Water Purification Systems (WPS) with recovery loops to minimize waste.
 - Conduct periodic energy and water audits.
 - Adopt renewable energy options (e.g., solar panels) where feasible.

9. Community complaints due to emissions, noise, or transport activities

- **Impact:** Nearby residents may be affected by generator noise, vehicular traffic, and odor emissions. This may cause dissatisfaction, complaints to regulators, and reputational risks for the company.
- **Mitigation:**
 - Maintain a Community Grievance Redressal Mechanism (GRM).
 - Schedule heavy transport during off-peak hours.
 - Implement noise and dust suppression at the facility boundary.
 - Engage in regular community consultations to address concerns.

10. Non-compliance with GMP, DRAP, or biosafety standards

- **Impact:** Failure to comply with GMP, DRAP, or biosafety standards may result in product recalls, regulatory penalties, suspension of operations, and reputational loss. It may also compromise public health by releasing unsafe diagnostic kits.
- **Mitigation:**
 - Strict adherence to GMP, ISO 13485, and DRAP guidelines.
 - Establish a dedicated Quality Assurance (QA) and compliance team.
 - Conduct periodic third-party audits and certifications.
 - Continuous staff training on biosafety and quality management.

8 ENVIRONMENTAL MANAGEMENT AND MONITORING PLAN

An Environmental Management and Monitoring Program (EMMP) is a structured framework developed to identify, mitigate, and monitor potential environmental impacts associated with the operations of M/S Apex Biotechnology. The primary objective of this program is to ensure compliance with national regulations, Good Manufacturing Practices (GMP), and environmental standards, while safeguarding the health of workers, surrounding communities, and natural ecosystems. The EIA has assessed both the positive and negative impacts of the project across design, construction, and operational phases, with particular attention to pharmaceutical effluents, solid and hazardous waste, energy consumption, and occupational safety. The EMMP outlines site-specific mitigation measures aligned with environmental sensitivities, DRAP requirements, and international best practices. It provides a practical guideline for management, contractors, and stakeholders to minimize adverse impacts and ensure sustainable operations. Furthermore, the EMMP will form an integral part of contract and compliance documents to facilitate effective environmental management, monitoring, and reporting throughout the project lifecycle.

8.1 Environmental Management Plan (EMP)

The EMP designed for the proposed project will ensure the following:

- Delivery of the prescribed environmental outcomes during all phases of this project.
- Formulating a system for compliance with applicable legislative requirements and obligations and commitments for this project.
- Ensure that the project incorporates environmentally sound design and sustainability principles to minimize potential impacts of construction and operation on the environment and community.
- Ensure that the construction and operation work procedures minimize potential impacts on the environment and community.
- Develop, implement and monitor measures that minimize pollution and optimize resource use.

8.2 Objectives of EMMP

The objectives of the EMMP are to promote sustainable and responsible pharmaceutical manufacturing practices, safeguard environmental quality, and ensure full compliance with national and international regulatory requirements. The specific objectives include:

- Implement measures to minimize emissions from generators, HVAC systems, and production processes to comply with Punjab ambient air quality standards.
- Ensure proper collection, treatment, and safe disposal of wastewater to prevent contamination of soil and groundwater.

- Adopt best practices for segregation, storage, and disposal of solid, packaging, and hazardous waste (e.g., solvents, expired drugs) in compliance with DRAP and environmental regulations.
- Maintain stringent GMP protocols and engineering controls to prevent cross-contamination between production areas.
- Minimize noise pollution from continuous machinery operation by adopting silencers, acoustic insulation, and scheduling maintenance.
- Protect workers from chemical exposure, ergonomic hazards, and accidents by implementing PPE use, safety trainings, and emergency preparedness plans.
- Promote energy efficiency and water conservation measures to reduce the plant's environmental footprint and ensure sustainable use of resources.
- Prevent adverse impacts (air, water, noise, traffic) on nearby communities and address concerns through effective grievance redress mechanisms.
- Ensure adherence to DRAP guidelines, GMP standards, and national environmental regulations throughout the plant's lifecycle.

8.3 Schedule for Implementation of Environmental Management Plan

In the proposed monitoring and evaluation framework, Apex Biotechnology will play a central role in overseeing and ensuring the effective implementation of the Environmental Management and Monitoring Program (EMMP). The company's management will integrate environmental considerations into its routine operational and compliance reporting systems, making environmental performance an essential component of overall business operations. To ensure day-to-day compliance and effective on-ground management, Apex Biotechnology will designate an in-house Environmental Consultant/Officer responsible for routine monitoring of air emissions, wastewater treatment, solid and hazardous waste management, occupational health and safety, and resource utilization. Findings will be compiled into internal reports and regularly communicated to senior management to maintain a real-time overview of environmental performance. Periodically, an independent Environmental Specialist will be engaged to conduct third-party audits of EMMP implementation. This specialist will review compliance with GMP standards, DRAP regulations, ISO 13485 requirements, and applicable environmental guidelines, providing objective feedback and recommending corrective measures where necessary. To strengthen credibility and transparency, Apex Biotechnology will also engage an independent validation body—such as an accredited environmental consultancy, recognized academic institute, or NGO—to review and validate EMMP implementation on an annual basis. At the regulatory level, the Provincial Environmental Protection Agency (EPA) will carry out inspections and compliance checks to ensure adherence to national environmental laws, PEQS for air and water quality, and hazardous waste management rules. In conclusion, the institutional framework for Apex Biotechnology is designed as a multi-tiered monitoring and evaluation system, combining internal oversight, independent audits, third-party validation, and EPA monitoring to ensure robust compliance and sustainable operations.

- Internal Monitoring by company-appointed Environmental Officer/Consultant.
- Periodic Audits by independent Environmental Specialists.
- Annual Third-Party Validation by accredited institutions or agencies.

- Regulatory Oversight by EPA at the provincial/district level.

This integrated approach ensures effective implementation of the EMMP, strengthens accountability, and promotes environmental sustainability across all stages of pharmaceutical manufacturing and operations.

8.4 Schedule for Implementation of Environmental Management Plan

The schedule for the implementation of the Environmental Management Plan (EMP) outlines a systematic timeline for executing key environmental management activities throughout the project. The schedule is designed to ensure the effective integration of environmental safeguards at various stages. The typical schedule may include

Table 8-1: Schedule for Implementation of Environmental Management Plan (EMP)

Phase	Key Activities	Responsibility
Pre-Construction	- Baseline environmental surveys (air, water, soil, noise) - Finalize EMP with DRAP/EPA approval - Secure land ownership & layout approval	Proponent, Environmental Consultant
Construction	- Dust & noise suppression measures - Safe storage of construction materials - Waste collection & disposal setup - Occupational health & safety training	Contractor, EHS Officer
Commissioning	- Install pollution control systems (air filters, scrubbers) - Safety & fire protection system inspection - Calibration of monitoring equipment	Contractor, EHS Officer
Trial Run	- Test production lines under controlled operation - Emission & effluent quality testing - Worker training on GMP, biosafety & hazardous material handling	Proponent, EHS Officer
Operational	- Enforce SOPs for emissions & effluent discharge - Proper hazardous waste segregation & disposal (expired drugs, solvents, packaging) - Regular fire, chemical spill & emergency drills	Facility Operator, EHS Team
Monitoring & Reporting	- Routine air, water, and noise monitoring - Solid & hazardous waste audits - Periodic compliance reports to EPA/DRAP - EMP updates as needed	EHS Officer, Third-Party Lab
Decommissioning (if required)	- Safe dismantling of equipment & machinery - Final hazardous waste disposal - Remediation/cleanup of contaminated areas	Contractor, EHS Officer
Post-Construction / Closure	- Site landscaping & green buffer development - Review & evaluation of EMP effectiveness - Submission of closure/environmental compliance	Proponent, Consultant

	report	
External Validation	- Independent environmental audit - Verification of DRAP/EPA compliance - Address audit findings	Independent Auditor, Proponent
Continuous Improvement	- Apply lessons learned to future expansion - Update SOPs & EMP based on new GMP/DRAP standards - Staff refresher trainings	Proponent, EHS Officer

This schedule for EMP implementation is adaptable and subject to adjustments based on monitoring findings, changes in project scope, or regulatory requirements. It emphasizes a proactive and adaptive approach, ensuring that environmental management measures are not only implemented effectively but also continually refined to achieve the project's environmental objectives.

8.5 Scope of Environmental Management Plan

The EMP provides mitigation and management measures for the following phases of the project:

8.5.1 Pre-Construction Phase

The scope of the Environmental Management Plan (EMP) during the pre-construction phase of the M/S Apex Biotechnology focuses on ensuring that all environmental and social safeguards are integrated into project planning and design before physical activities commence. This includes obtaining necessary environmental approvals and NOCs from relevant authorities, ensuring compliance with PEQS and incorporating environmental considerations into technical designs. The EMP also covers site verification to avoid environmentally sensitive areas, planning for safe storage and handling of materials, and developing mitigation strategies for anticipated impacts. Additionally, this phase emphasizes meaningful stakeholder engagement, public disclosure of project-related information, and the establishment of grievance redress mechanisms. These actions are critical for identifying and addressing potential risks early, ensuring regulatory compliance, and setting a strong foundation for environmental management during construction and operation phases.

8.5.2 Construction Phase

This section of EMP provides management principles for the construction phase of the project. Environmental actions, procedures and responsibilities as required within the construction phase are specified. These specifications will form part of the contract documentation and therefore, the contractor will be required to comply with the specifications to the satisfaction of the project Manager and Environmental Control Officer, in terms of the construction contract.

Table 8-2: Key Environmental Management Actions

Activity	Potential Impact	Mitigation Measures	Responsible Party
Site Preparation & Construction	Soil erosion, minor habitat disturbance	Limit clearing to designated areas; use silt fences; replant vegetation where feasible	Contractor, EHS Officer
Material Storage (Chemicals, Solvents, Raw Materials)	Soil & water contamination, fire hazard	Store on impervious surfaces with bunds; use proper labeling & MSDS; fireproof storage for flammables	Contractor, EHS Officer
Pharmaceutical Waste Handling	waste mismanagement, infection risks	Segregate waste; dispose through licensed facility.	Facility Operator, EHS Officer
Air Emissions (Dust, Fumes, Solvent Vapors)	Air pollution, worker health risks	Install air scrubbers/filters; ensure proper ventilation; enclose dust-generating operations	Contractor, Facility Operator
Noise from Equipment & Generators	Disturbance to workers and nearby communities	Use low-noise machinery; provide ear protection to workers; restrict heavy operations to working hours	Contractor, EHS Officer
Chemical & Fuel Spillages	Soil, groundwater contamination, fire/explosion risk	Secondary containment; spill response kits; staff training on spill control & emergency response	Contractor, EHS Officer
Worker Safety & Health	Accidents, injuries, exposure to hazardous substances	Provide PPE (gloves, masks, goggles); safety training; regular medical checkups; enforce GMP & OHS standards	Facility Operator, EHS Officer
Energy & Utility Use (Generators, HVAC)	GHG emissions, resource depletion	Use energy-efficient systems; regular maintenance of gensets; explore renewable energy options	Facility Operator, EHS Team
Packaging & Solid Waste	Litter, environmental pollution	Segregate recyclable materials (cartons, plastics); safe disposal of contaminated packaging	Facility Operator, Contractor

8.6 Operation and Mitigation Phase

This section of EMP provides management principles for the operation and maintenance phase of the project. Environmental actions, procedure and responsibilities are required from proponent within the operation and maintenance phase are satisfied.

8.7 Environmental Plan for Construction and Operation Phase

Table 8-3 Environmental Management Plan for Construction Phase

Sr NO.	Project Component/ Impact	Mitigation/ Preventive Action	Responsibility	
			Implementation	Monitoring
Design/Pre-Construction Phase				
1.	Improper facility design leading to GMP non-compliance	The following measures will be implemented: <ul style="list-style-type: none"> Engage qualified consultants for facility design; ensure compliance with MHRA/FDA & EU GMP guidelines; integrate cleanroom standards. 	During Pre-Construction Phase	Proponent and Contractor
2.	Incorrect siting near residential / sensitive receptors	<ul style="list-style-type: none"> Conduct site suitability & EIA; maintain buffer distance from residences, schools, and hospitals; comply with PEQS/local siting rules. 	During Pre-Construction Phase	Proponent and Contractor
3.	Use of substandard equipment or technology	The following measures will be implemented <ul style="list-style-type: none"> Specify validated pharma-grade equipment (HVAC, water systems, clean steam); third-party quality assurance during procurement. 	During Pre-Construction Phase	Proponent and Contractor
4.	Risk of cross-contamination due to poor layout	The following measures will be implemented <ul style="list-style-type: none"> Design unidirectional flow of materials & personnel; separate hazardous & non-hazardous production zones; use airlocks & pressure differentials. 	During Pre-Construction Phase	Proponent and Contractor

5.	Improper waste disposal design (solvents, APIs)	The following measures will be implemented <ul style="list-style-type: none"> • Provide dedicated storage with bunds; specify approved disposal facility. 	During Pre-Construction Phase	Proponent and Contractor
6.	Occupational health risks (chemical exposure, dust inhalation)	The following measures will be implemented: <ul style="list-style-type: none"> • Provide PPE (masks, gloves, goggles); establish MSDS-based handling SOPs; safety training during commissioning. 	During Pre-Construction Phase	Proponent and Contractor
7.	Flooding / fire risk affecting pharma site	The following measures will be implemented: <ul style="list-style-type: none"> • Avoid siting in flood-prone areas; construct raised foundations; install fire fighting & stormwater drainage systems. 	During Pre-Construction Phase	Proponent and Contractor

Constructional Phase

1	Degradation of air quality due to construction works	The following measures will be implemented: <ul style="list-style-type: none"> • Unpaved areas and construction roads will be regularly sprinkled with water to suppress dust, especially during dry and windy conditions. • Construction materials prone to dust generation (e.g., cement, sand) will be covered and stored in designated enclosures. • Vehicles transporting materials will be covered with tarpaulin to prevent material spillage and dust dispersion. • All construction machinery and vehicles will 	During construction phase	Proponent and Contractor
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		<p>be maintained in good condition and comply with PEQS for emissions.</p> <ul style="list-style-type: none"> • Idle running of construction machinery will be avoided, and equipment will be shut off when not in use. • Air quality monitoring will be carried out during the construction phase in accordance with PEQS standards. • Personal Protective Equipment (PPE) such as dust masks will be provided to all construction workers. 		
2	<p>Soil erosion and cutting of roads/pavements due to excavations</p>	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Excavation work will be planned and executed in phases to minimize the duration and extent of exposed soil. • Proper shoring, bracing, or trench boxes will be used to stabilize excavated areas and avoid collapse. • Temporary or permanent drainage channels will be provided to direct runoff and prevent erosion. • Excavated soil will be reused for backfilling where feasible, or stored in designated locations with appropriate covers and bunds. • Damaged roads or pavements will be promptly repaired and restored to original condition after completion of underground works. • Warning signs, barricades, and alternative 	During construction phase	Proponent and Contractor

		<p>pathways will be provided to ensure public and worker safety.</p> <ul style="list-style-type: none"> • All construction debris and loose soil will be removed from public roads on a daily basis to maintain cleanliness and reduce dust emissions. 		
3	Traffic management issues	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • A traffic management plan will be developed in coordination with local traffic authorities. • Construction vehicle movement will be scheduled during off-peak hours. • Clear signage and flagmen will be deployed at key junctions and entry/exit points. • Emergency vehicle access to the hospital will be ensured at all times. • Speed limits and movement restrictions will be imposed on heavy vehicles near sensitive areas. • Temporary diversions will be created where road closures are unavoidable. 	During construction phase	Proponent and Contractor
4	Community health and safety risks	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Construction sites will be fenced and access controlled with appropriate warning signage. • Community awareness sessions will be held to inform locals about construction risks. 	During construction phase	Proponent and Contractor

		<ul style="list-style-type: none"> • Regular site disinfection and waste disposal will be conducted to minimize health risks. • All construction workers will undergo health screening and receive awareness on hygiene practices. • First aid kits and trained personnel will be available on site. 		
5	Occupational health and safety hazards	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Induction training on safety procedures will be provided to all workers. • Workers will be equipped with appropriate PPE including helmets, gloves, masks, ear protection, and high-visibility vests. • Workplace signage will be installed to indicate hazard areas. • First aid facilities and trained personnel will be available on site at all times. • Regular health check-ups and safety drills will be conducted. • Emergency response plans will be in place and communicated to all staff. 	During construction phase	Proponent and Contractor
6	High noise levels from construction activities	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Construction activities will be limited to daytime hours (e.g., 8:00 AM to 6:00 PM) to minimize community disturbance. • High-noise equipment will be maintained regularly to reduce excess noise. 	During construction phase	Proponent and Contractor

		<ul style="list-style-type: none"> • Noise barriers or acoustic sheets will be installed near noise-intensive zones, especially near hospital buildings. • Workers will be provided with ear protection devices such as earplugs or earmuffs. • Ambient noise monitoring will be conducted periodically to ensure compliance with PEQS. 		
7	Improper handling/disposal of hazardous and non-hazardous waste	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Hazardous and non-hazardous waste will be segregated at source and stored in designated containers with labels. • Authorized waste disposal contractors will be engaged for collection and treatment in accordance with EPA guidelines. • Waste storage areas will be paved, covered, and leak-proof to prevent contamination. • Staff will be trained in hazardous waste handling procedures. • Records of waste generation and disposal will be maintained and made available for inspection. 	During construction phase	Proponent and Contractor
9	Untreated disposal of effluent from worker camps or batching plants	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Worker camps will be equipped with septic tanks or bio-digesters for wastewater treatment. • Concrete batching plants will have 	During construction phase	Proponent and Contractor

		<p>sedimentation tanks or recycling pits for slurry and wash water.</p> <ul style="list-style-type: none"> • No untreated effluent will be allowed to discharge into stormwater drains, canals, or open land. • Regular inspections will ensure proper maintenance and functioning of treatment facilities. • Effluent testing will be conducted periodically to ensure compliance with PEQS. 		
10	Soil contamination due to accidental spills or poor storage	<ul style="list-style-type: none"> • All hazardous liquids will be stored in spill-proof containers over impervious surfaces. • Storage areas will be equipped with secondary containment (bunds or trays). • Spill kits and trained personnel will be available on-site for immediate response. • In case of spills, contaminated soil will be removed and disposed of at authorized facilities. • Regular inspections will be conducted to identify potential leakages early. 	During construction phase	Proponent and Contractor
11	Employment-related conflicts	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Preference will be given to qualified local workers during recruitment. • A clear, transparent, and merit-based hiring policy will be adopted and communicated. • A grievance redress mechanism will be established to address worker concerns. 	During construction phase	Proponent and Contractor

		<ul style="list-style-type: none"> • Regular communication will be maintained with community leaders to manage expectations. • Awareness programs will be conducted to promote workplace harmony and tolerance. 		
12	Gender issues including gender-based violence (GBV)	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • A strict code of conduct will be enforced to prevent any form of harassment or abuse. • Awareness training on gender sensitivity, GBV prevention, and reporting procedures will be conducted for all staff. • Separate sanitation facilities will be provided for male and female workers. • A confidential reporting mechanism for GBV will be established. • Local women will be encouraged to apply for suitable employment opportunities. 	During construction phase	Proponent and Contractor
13	Vegetation and wildlife loss due to land clearance	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Clearing will be limited strictly to the required footprint of construction. • Where feasible, existing vegetation will be preserved and protected. • Replanting or compensatory plantation will be carried out using native species post-construction. • Site boundaries will be clearly marked to prevent unauthorized clearing. • Awareness will be raised among workers 	During construction phase	Proponent and Contractor

		about wildlife protection and prohibitions on hunting.		
15	Social tensions resulting from influx of labor	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Non-essential labor will be sourced locally to reduce influx. • Workers will be briefed on local customs and respectful conduct. • Contractors will provide on-site accommodation to minimize community interactions and resource competition. • Grievance mechanisms will be established for community members to report labor-related concerns. • Community liaison officers will be appointed to facilitate communication and manage relationships. 	During construction phase	Proponent and Contractor
16	Use of child labor	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Strict age verification will be carried out during recruitment; national legal age limits will be enforced. • All contractors and subcontractors will be contractually bound to prohibit child labor. • Unannounced inspections and audits will be conducted to monitor labor practices. • Training sessions will be held to educate all site managers on labor laws and ethical hiring. 	During construction phase	Proponent and Contractor

17	Loss of access to facilities or roads	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • Access routes will be kept open at all times, particularly for emergency and hospital vehicles. • Where temporary closures are unavoidable, alternative routes will be clearly marked and communicated in advance. • Construction will be planned in phases to minimize obstruction. • Warning signs, flagmen, and directional boards will be installed to guide traffic and pedestrians. • Close coordination with local authorities and community members will be maintained. 	During construction phase	Proponent and Contractor
18	Site restoration concerns post-construction	<p>The following measures will be implemented:</p> <ul style="list-style-type: none"> • All temporary structures, machinery, and waste will be removed post-construction. • Damaged surfaces, vegetation, and pavements will be restored to pre-construction conditions. • A site-specific restoration plan will be developed and approved by relevant authorities. • Post-construction inspection will be carried out to ensure compliance with restoration requirements. • Native vegetation will be replanted to stabilize soil and enhance aesthetics. 	During construction phase	Proponent and Contractor

8.8 Environmental management team along with their roles and responsibilities

The project proponent bears the responsibility for overseeing all the project activities. To cater to the varying requirements during operational phase, the proponent will hire personnel specifically dedicated to environmental management at the project site. This step is crucial to ensure the effective implementation and operations of the EMP.

Assigning the responsibilities to designated individuals is paramount to uphold accountability in the event of any oversight or mishap. Each appointed person will have specific duties outlined within the EMP. These responsibilities will be tailored to their roles, ensuring they are accountable for the successful execution of environmental protocols and procedures.

By delineating and assigning these responsibilities to individuals, the project proponent establishes a framework where each person understands their role and obligation within the broader context of environmental management. This structuring allows for a more efficient response to any environmental issue. This approach aims to create a clear chain of accountability, ensuring that the implementation of EMP is conducted diligently and that there are identifiable points of contact for any concerns or queries related to environmental management during the project's operational phase.

8.9 Environmental Monitoring Program

An Environmental Monitoring Plan (EMP) is a structured system designed to consistently observe, assess, and record the environmental conditions and impacts associated with the construction and operation of a IVD Medical reagents manufacturing facility. It involves systematic data collection related to air quality, wastewater, soil conditions, chemical residues, and biodiversity. The collected data is analyzed to detect any deviations from the prescribed environmental quality standards (PEQS).

The EMP also covers impact assessments, communication of findings with regulatory bodies and stakeholders, and adaptive management – making necessary adjustments to mitigate environmental risks such as hazardous waste, chemical emissions, or pharmaceutical residues in effluents. The program's ultimate goal is to ensure sustainable environmental practices, minimize adverse impacts, and maintain compliance with regulatory standards, thus contributing to safe operations and long-term sustainability

8.10 Objectives of the Environmental Monitoring Plan (EMP)

- Detect environmental changes arising from pharmaceutical production activities (e.g., solvent emissions, wastewater discharge, or chemical spills) to prevent and minimize potential negative impacts.
- Ensure compliance with environmental laws, permits, and regulations by conducting regular monitoring and reporting of pharmaceutical-related parameters (such as COD, BOD, heavy metals, and microbial contamination). This helps in meeting legal requirements and avoiding penalties.
- Assess and manage risks posed by pharmaceutical operations, including the handling of hazardous chemicals, solvents, and effluents, by evaluating impacts and implementing mitigation measures.
- Monitor and manage natural resources (water, energy, and air) to ensure efficient use and conservation, while maintaining ecological balance in and around the plant.
- Assess the impact of manufacturing processes on the environment to understand their consequences (e.g., wastewater quality, air emissions, solid and hazardous waste) and guide improvements in plant operations.
- Improve environmental performance by using collected data to refine treatment processes, enhance waste management systems, and adopt best available technologies.
- Establish emergency response protocols for unexpected environmental incidents (chemical spills, leakage of solvents, fire hazards), ensuring quick and effective mitigation to minimize environmental damage.

Table 8-4: Environmental Monitoring Plan for Pharmaceutical Industry

Sr. No	Monitoring Parameters	Monitoring Location	Monitoring Mechanism	Remarks
A. Construction Phase				
1	Noise	Construction vehicles, machinery, generators, welding/fabrication work	Noise meter	Construction vehicles/machinery/generators will be checked regularly for noise levels by the contractor during construction phase.
2	Air Emissions	Construction	Ambient	Regular checks of vehicles and

	(Dust, Smoke)	vehicles, machinery, generators	particulate matter (PM ₁₀ , PM _{2.5}) monitoring	machinery for emissions by the contractor during construction phase.
3	Wastewater	Temporary worker camps, site drainage points	Visual inspection & basic water quality tests (pH, turbidity, BOD)	Wastewater will be monitored to prevent contamination during construction phase.
4	Solid Waste	Construction site & worker camps	Visual inspection, segregation	Solid waste will be collected, segregated, and disposed of properly by the contractor.

B. Operation Phase

1	Air Emissions (Solvent Vapors, Dust)	Production units, storage areas, exhaust outlets	Stack/ambient air quality monitoring (VOC, PM, NO _x , SO ₂)	Monitoring on quarterly basis as per PEQS and pharmaceutical GMP standards.
2	Wastewater Monitoring	Effluent discharge points, ETP (Effluent Treatment Plant) outlet	Testing for pH, COD, BOD, TDS, residual solvents, microbial contamination	Monitoring will be carried out monthly/quarterly to ensure compliance with standards.
3	Hazardous Waste	Storage areas, disposal sites	Inspection, inventory checks, compliance with hazardous waste handling rules	Monthly monitoring to ensure proper handling and disposal through licensed vendors.
4	Occupational Health & Safety	Production floors, laboratories, storage tanks	Workplace monitoring for noise, temperature, solvent exposure, microbial load	Periodic monitoring as per HSE plan.
5	Pharmaceutical Residues in Environment	Treated wastewater outlet, soil around disposal areas	Laboratory analysis for APIs (Active Pharmaceutical Ingredients) and	Carried out on six-monthly basis to ensure no pharmaceutical residues contaminate the environment.

		residues	
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8.11 Environmental Budget

An environmental budget is an essential part of IVD medical reagents manufacturing project, ensuring funds are allocated for environmental protection, compliance, and sustainability. It covers costs for waste management, wastewater treatment, air emission control, energy efficiency, and compliance with regulations. The budget also includes expenses for environmental monitoring, staff training, and routine audits to ensure Good Manufacturing Practices (GMP) and minimal ecological impact. This allocation helps the facility operate responsibly while supporting long-term environmental sustainability.

Table 8-5: Environmental Budget

Environmental Component	Amount (PKR)	Details	Remarks
A. Environmental Management Cost			
Fire, Health & Safety Measures	250,000	Provision of PPE, fire extinguishers, alarms, emergency exits, safety signage	To be included in Project Budget
Wastewater & Effluent Management	300,000	Installation/operation of small-scale Effluent Treatment System (ETS)	To ensure compliance with PEQS
Solid & Hazardous Waste Management	150,000	Safe storage, segregation, and disposal through licensed contractors	To prevent soil & water contamination
B. Environmental Monitoring Cost			
Air, Water & Noise Monitoring	180,000	Regular monitoring (quarterly/annual) as per EPA standards	To be included in Project Budget
Third-party Environmental Audits	70,000	Independent verification of EMP/EMMP compliance	Required by regulatory bodies
C. Green Initiatives	30,000	Tree plantation and landscaping around facility	For ecological balance & aesthetics
D. Contingency / Emergency Response	20,000	For accidental spills, leaks, or unforeseen events	Buffer allocation
Total Environmental Management and Monitoring Cost	1,000,000	(A + B + C + D)	To be included in Project Budget

9 FIRE SAFETY PLAN

A fire safety plan is a structured and comprehensive document that details procedures, protocols, and strategies aimed at preventing, preparing for, and responding to fire emergencies at the project site. This essential plan outlines preventive measures, emergency procedures, evacuation protocols, fire detection and suppression systems, training requirements and communication strategies. It assigns specific roles and responsibilities to individuals and provides clear instructions for evacuations, ensuring occupants, or employees understand what to do in case of a fire. Regular reviews and updates to the plan maintain its relevance, ensuring compliance with fire safety regulations and fostering a safe and prepared environment in the event of a fire emergency.

9.1 Objectives of a fire safety plan

Following objectives collectively aim to create a safe and prepared environment in the face of a fire emergency, ensuring the protection of lives, property, and assets.

- ✓ The primary goal is to prevent fires from occurring by implementing measures that reduce fire hazards, ensuring that all the safety systems, equipment, and protocols are up to standard, and that fire risks are minimized.
- ✓ Protecting the lives and well-being of occupants and employees by ensuring a quick and safe evacuation during a fire emergency. This involves establishing and regularly practicing efficient evacuation routes and procedures.
- ✓ Minimizing damage to property and assets by having effective fire detection and suppression systems in place. This includes regular maintenance of fire safety equipment such as fire alarms, sprinkler systems, and fire extinguishers.
- ✓ Outlining procedures to respond effectively and efficiently in the event of a fire. This involves establishing clear roles and responsibilities for personnel during a fire emergency.
- ✓ Ensuring compliance with local fire safety regulations and standards.
- ✓ Conducting regular training sessions, and fire drills to educate occupants and employees about fire safety procedures, evacuation routes, and the use of fire equipment.

- ✓ Regularly reviewing and updating the fire safety plan to incorporate any necessary changes in equipment, procedures, or regulations. This ensures the plan remains current and effective.

9.2 Fire Safety Symbols

In Pharmaceutical industries, hazard identification symbols play a crucial role in communicating potential hazards identification symbols play a crucial role in communicating potential dangers to employees, emergency responders, and the public. These symbols, often standardized, convey various hazard associated with the storage and handling of materials. Some common symbols and their meanings in such a facility include:

9.2.1 Flammable Symbol

It warns about the potential for fire explosion.



Figure 9-1: Symbol for Flammable Material

9.2.2 Gas Cylinder Symbol

It highlights the presence of compressed gas cylinder, signifying the potential pressure and hazards associated with gas containment.



Figure 9-2: Symbol for Gas Cylinder

9.2.3 Toxic Symbol

It warns about the toxicity of certain chemicals or gases, emphasizing the need for caution and proper handling to avoid health and hazard.



Figure 9-3: Symbol for Toxic Material

9.2.4 Explosive Symbol

It indicates the potential for an explosion due to certain conditions or elements present in the industry.



Figure 9-4: Symbol for Explosive Material

9.2.5 Electrical Hazard Symbol

It warns about electrical hazards present in the facility, highlighting the risk of electrical shock or short circuits.



Figure 9-5: *Symbol for Electrical Hazard*

9.2.6 PPE (Personal Protective Equipment) Symbol

It emphasizes the necessity of wearing appropriate personal protective equipment while working in the facility.



Figure 9-6: Symbols of PPEs

9.2.7 Environmental Hazard Symbol

It signifies potential hazards to the environment, like contamination or pollution risks from leaks.



Figure 9-7: Environmental Hazard Symbol

These symbols are commonly used in combination with written warnings, color codes, and other safety measures to ensure a comprehensive and easily understandable identification system for the hazards present in pharmaceutical unit. It's crucial for all personnel to be familiar with these symbols and their meanings to ensure a safe working environment.

9.3 Fire Safety Measures

Fire safety measures prevent fires and explosions, safeguard personnel, protect property and equipment, ensure compliance with regulations, maintain emergency preparedness, and mitigate environmental risks associated with potential fire incidents. Following safety measures are proposed at project site.

FIRE EXTINGUISHERS

Fire extinguishers are necessary in storage areas of the facility. They provide a means to quickly suppress small fires, prevent their escalation, comply with safety regulations, and protect lives, and the environment. These extinguishers ensure emergency preparedness and the rapid containment of fires, offering immediate response and safety for individuals working in or around storage areas.

9.3.1 Dry Chemical Powder Fire Extinguishers

Dry Chemical Powder (DCP) fire extinguishers are an essential safety measure in pharmaceutical facilities due to their ability to combat different classes of fires, including those involving chemicals, solvents, and electrical equipment. In pharmaceutical operations, where flammable substances and sensitive machinery are present, DCP extinguishers are highly effective as they interrupt the chemical reaction of the fire, quickly suppress flames, and minimize the risk of escalation. They are particularly useful for Class B fires (flammable liquids such as alcohols and solvents) and Class C fires (electrical equipment), which are common risks in laboratories, production areas, and storage facilities. Their reliability, fast action, and versatility make DCP fire extinguishers a critical component of pharmaceutical safety protocols, ensuring protection of personnel, equipment, and valuable research asset



Figure 9-8: DCP Fire Extinguisher

9.3.2 Fire Extinguishers Foam Type

Fire extinguishers of the foam type play a critical role in ensuring the safety of pharmaceutical facilities. Pharmaceutical operations often involve the use of flammable liquids such as alcohols, solvents, and chemicals, which can pose significant fire hazards if not properly managed. Foam-type extinguishers are specifically designed to combat flammable liquid fires, making them indispensable in laboratories, production areas, and chemical storage units. The foam creates a blanket over the liquid surface, suppressing the release of flammable vapors and effectively preventing the spread of fire. This targeted mechanism allows for swift and effective control of fire outbreaks, reducing the risk of damage to sensitive equipment, stored medicines, and valuable research materials.

The use of foam extinguishers in pharmaceutical facilities highlights a proactive safety measure, ensuring reliable first response in the event of fire emergencies and safeguarding personnel, assets, and the surrounding environment. Regular maintenance, periodic training on proper usage, and adherence to strict safety protocols further enhance the effectiveness of foam-type fire extinguishers in protecting pharmaceutical operations.



Figure 9-9: Fire Extinguisher Foam Type

9.3.3 Fire Hydrants

Fire Hydrants provide immediate access to water for firefighting in emergencies, supporting fire suppression efforts, ensuring site safety by cooling structures, and complying with safety regulations. Although water might not directly extinguish fires, hydrants serve as a crucial resource for firefighting equipment and overall emergency preparedness.



Figure 9-10: Fire Hydrant

9.3.4 Fire Alarm

Fire alarms are crucial for early fire detection, timely warnings, evacuation, facilitation, prevention of fire escalation, and compliance with safety regulations. They play a vital role in ensuring the safety of personnel and protecting the facility and its surroundings. Fire alarm is supposed to be installed at the storage plant.



Figure 9-11: Fire Alarm

9.3.5 Sand Buckets

Sand buckets hold significant importance in the safety measures. In the event of a small fire or a minor leak that may lead to a fire, sand buckets provide a crucial first line of defense. Sand is a

non-combustible material, and when swiftly applied to a small flame, it can smother the fire by cutting off its oxygen supply. Moreover, in cases where liquid chemicals are involved, sand can be used to absorb and neutralize spills. The use of sand buckets is particularly essential in situations where traditional firefighting equipment, like water or foam, may not be suitable due to the flammable nature of certain components. These buckets are strategically placed throughout the facility, easily accessible for immediate use, and serve as an additional safety measure to contain and control potential fire hazards effectively. Regular training and awareness regarding the proper use of sand buckets will further enhance their role in maintaining a secure environment. Fire Sand Bucket will be placed to cater any minor fire accident.



Figure 9-12: Sand Bucket

9.3.6 Fire Pump

A fire pump holds paramount importance in the safety infrastructure of a pharmaceutical facility. The presence of flammable chemicals, solvents, and alcohol-based solutions used in production and laboratory processes necessitates rapid and effective fire response mechanisms. A fire pump is a critical component of the facility's firefighting system, as it ensures a pressurized and reliable water supply during emergencies. In the event of a fire outbreak, the pump activates to deliver water at high pressure to firefighting hoses and nozzles, enabling responders to swiftly extinguish or control the fire and prevent its escalation. The installation of fire pumps in pharmaceutical plants addresses challenges related to water distribution, especially in large production areas or multi-story buildings where consistent water pressure is vital. Their presence significantly enhances firefighting capacity, ensuring protection of sensitive

equipment, stored medicines, raw materials, and personnel. Regular inspection, maintenance, and performance testing of fire pumps are essential to guarantee their operational readiness and reliability in safeguarding pharmaceutical operations against fire emergencies.



Figure 9-13: Fire Pump

9.3.7 Jockey Pump

The jockey pump plays a crucial role in maintaining the operational efficiency and safety of fire protection system. This small but vital pump ensures that the fire suppression system's main piping remains pressurized within an optimal range. By doing so, the jockey pump helps prevent unnecessary cycling of the main fire pump and ensures that it only activates when there's an actual fire emergency. This not only conserves energy but also extends the lifespan of the main pump, reducing wear and tear. The jockey pump contributes to the plant's readiness to respond swiftly and effectively to fire incidents by maintaining the required pressure in the fire protection system, guaranteeing that water or fire suppression agents can be delivered promptly when needed. Regular monitoring and maintenance of the jockey pump will essential to ensure its reliability, making it an integral component of the overall fire safety strategy at the pharmaceutical facility.



Figure 9-14: Jockey Pump

9.3.8 Standby Pump

The standby pump is a critical component in ensuring the reliability and continuous functionality of the fire protection system at English Pharmaceutical industry. In the event that the primary fire pump faces mechanical failure or requires maintenance, the standby pump serves as a backup, ready to seamlessly take over the crucial task of maintaining water pressure for fire suppression. This redundancy is vital for preventing any downtime in the plant's ability to respond promptly to fire emergencies. The standby pump ensures that there is no compromise in the fire protection system's effectiveness, providing a constant and reliable water supply even during unexpected failures. This redundancy not only enhances the overall safety of the industry but also contributes to the resilience of the plant's fire safety infrastructure, ensuring uninterrupted protection against potential fire hazards. Regular testing and maintenance of the standby pump will be imperative to guarantee its operational readiness when called upon.

10 OCCUPATIONAL HEALTH AND SAFETY PLAN

The Occupational Health and Safety (OHS) plan holds paramount importance within the framework of an EIA. This plan is a comprehensive document that outlines strategies and protocols to safeguard the well-being of workers involved in the project. Beyond the ethical imperative of ensuring a safe working environment, the OHS plan is integral to regulatory compliance and risk management. It identifies potential occupational hazards associated with the project, establishes preventive measures, and details emergency response procedures. By incorporating an OHS plan into the EIA, not only is the health and safety of the workforce prioritized, but it also contributes to the overall success and sustainability of the project. A well-executed OHS plan minimizes the likelihood of accidents, injuries, and occupational health issues, fostering a workplace culture that values the welfare of its personnel. In essence, the OHS plan, as part of the EIA process, aligns with responsible and ethical project management, ensuring that occupational health and safety considerations are seamlessly integrated into the project's design, implementation, and ongoing operations.

10.1 Objectives of Occupational Health and Safety

The objectives of Health and Safety plan at English pharmaceutical industry are given below

- ✓ Protect the health and safety of employees, contractors, visitors, and nearby communities by preventing workplace injuries, occupational illnesses, chemical exposures, and fire hazards.
- ✓ Minimize risks associated with pharmaceutical operations, including the handling of flammable chemicals, solvents, and biological materials, ensuring safe storage, processing, and disposal practices.
- ✓ Ensure compliance with all applicable health, safety, and environmental regulations, Good Manufacturing Practices (GMP), and international standards relevant to pharmaceutical operations.
- ✓ Promote a safe working culture by providing training, personal protective equipment (PPE), and emergency preparedness measures for fire, chemical spills, or accidental releases.

- ✓ Safeguard the environment by preventing contamination of air, water, and soil from pharmaceutical waste, emissions, and hazardous materials.
- ✓ Support continuous improvement in health and safety performance through regular monitoring, audits, and corrective actions.

10.2 Scope of Occupational Health and Safety Plan

The Occupational Health and Safety (OHS) framework at English Pharmaceutical Industry will cover the following areas:

- Workplace Safety – Implementation of safe work practices to prevent accidents, injuries, and occupational illnesses across production, laboratories, warehouses, and administrative areas.
- Chemical Safety – Safe handling, storage, labeling, and disposal of active pharmaceutical ingredients (APIs), solvents, and other hazardous substances.
- Biological Safety – Control measures for handling biological agents and materials to protect employees and the surrounding community.
- Fire and Explosion Safety – Installation and maintenance of firefighting equipment, alarms, and emergency response systems to address risks from flammable chemicals and processes.
- Personal Protective Equipment (PPE) – Provision, use, and monitoring of PPE such as gloves, masks, goggles, and lab coats to reduce exposure risks.
- Health Surveillance & Medical Services – Regular health check-ups, occupational health screenings, and first-aid facilities for employees.
- Training and Awareness – Continuous education and training programs for employees and contractors on safe practices, emergency response, and hazard identification.
- Emergency Preparedness & Response – Development of evacuation plans, spill management procedures, and fire drills to ensure rapid and effective responses to emergencies.
- Regulatory Compliance – Strict adherence to OSHA, WHO, GMP, ISO, and national occupational health and safety standards applicable to the pharmaceutical sector.
- Continuous Improvement – Regular monitoring, auditing, and reviewing of OHS performance for ongoing enhancement of workplace safety.

10.3 PERSONAL PROTECTIVE EQUIPMENT

The use of Personal Protective Equipment in a paper manufacturing plant is vital for safeguarding workers, ensuring regulatory compliance, mitigating risks, and promoting a culture of safety that is conducive to both employee well-being and operational excellence. The importance of Personal Protective Equipment (PPE) at a paper manufacturing plant cannot be overstated. Here are several key reasons highlighting the significance of PPE in this industrial setting:

- PPE provides a crucial line of defense against various occupational hazards prevalent in a paper manufacturing environment. It includes items such as safety helmets, gloves, safety glasses, and respiratory protection, which shield workers from potential injuries, chemical exposures, and airborne particles.
- Utilizing PPE is often a legal requirement and is mandated by occupational health and safety regulations. Adhering to these regulations not only ensures the safety of workers but also prevents regulatory penalties and legal issues for the manufacturing unit.
- Paper manufacturing involves machinery, chemicals, and processes that pose inherent risks. PPE serves as a risk mitigation strategy by minimizing the likelihood and severity of injuries or illnesses, contributing to a safer working environment.
- In the paper manufacturing process, workers may come into contact with various chemicals used in pulping, bleaching, and other stages. PPE, such as chemical-resistant gloves and protective clothing, safeguards workers from direct skin contact and potential harm.
- Dust and other airborne particles are common in paper mills. Respiratory protection, such as masks or respirators, is vital in preventing inhalation of harmful substances, promoting respiratory health, and minimizing the risk of respiratory-related illnesses.

- PPE not only prioritizes safety but also contributes to the overall comfort of workers. Comfortable and well-fitted PPE encourages adherence to safety protocols, fostering a positive work culture and enhancing overall productivity.
- In the event of unexpected incidents or emergencies, PPE can be crucial for protecting workers and mitigating the impact of accidents. Items like hard hats and steel-toed boots provide added protection during emergencies.
- Providing PPE demonstrates the employer's commitment to the health and safety of its workforce, instilling confidence and trust among employees. This, in turn, contributes to a positive work environment and employee morale.

10.4 PPE REQUIRED FOR CONSTRUCTION PHASE

During the construction of a project, including a paper manufacturing unit, a comprehensive set of Personal Protective Equipment (PPE) is necessary to safeguard the health and safety of workers involved in various tasks. The specific PPE requirements may vary based on the nature of construction activities, potential hazards, and regulatory standards. Here is a general list of PPE commonly required during construction:

Head Protection: Hard hats to protect against falling objects, impact, or head injuries.

Eye and Face Protection: Safety glasses or goggles to shield the eyes from dust, debris, or other airborne particles. Face shields for additional protection during tasks with a higher risk of facial exposure.

Hearing Protection: Earplugs or earmuffs to reduce exposure to loud noises, especially in areas with heavy machinery or construction equipment.

Respiratory Protection: Dust masks or respirators to protect against inhalation of dust, particulates, or hazardous substances.

Hand Protection: Safety gloves appropriate for the specific tasks, such as cut-resistant gloves, leather gloves, or chemical-resistant gloves.

Body Protection: High-visibility vests or clothing to enhance visibility, especially in areas with moving equipment. Reflective clothing for night time or low-visibility construction activities. Protective clothing, such as coveralls, for tasks involving exposure to hazardous substances.

Foot Protection: Steel-toed safety boots or shoes to protect against crushing injuries, falling objects, or punctures.

Fall Protection: Safety harnesses, lanyards, and other fall protection systems for workers operating at heights or in elevated areas.

Hand and Arm Protection: Elbow and knee pads for tasks that involve kneeling or crawling. Wrist support or braces for tasks with repetitive motions.

Weather Protection: Weather-appropriate clothing, such as rain gear, insulated clothing, or sunscreen, depending on the climate and weather conditions.

First Aid Kit: Access to a well-equipped first aid kit to provide immediate care for minor injuries.



Figure 10-1: PPEs for Construction Phase

It is essential for the construction project management to conduct a thorough hazard assessment to identify the specific risks associated with each construction activity and determine the appropriate PPE for the workers involved. Regular training, monitoring, and enforcement of PPE usage contribute to a safer construction environment.

10.5 SAFETY SIGNS DURING CONSTRUCTION PHASE

Safety signs serve as critical elements in maintaining a secure and hazard-free environment at construction sites. Their importance lies in their ability to effectively communicate potential risks

and hazards to workers, visitors, and contractors. By providing clear information about safety procedures, required personal protective equipment, and safe work practices, these signs play a pivotal role in preventing accidents and injuries. Moreover, safety signs contribute to regulatory compliance, ensuring adherence to local regulations and occupational health and safety standards. They also serve as essential tools for emergency response by indicating the location of emergency exits, first aid stations, fire extinguishers, and other emergency equipment. In addition to their role in risk reduction, safety signs assist in site navigation, guiding individuals to specific areas and enhancing overall organization. Beyond practical benefits, safety signs contribute to fostering a culture of safety awareness among the workforce. They communicate important safety policies, promote compliance with site-specific regulations, and reduce the project's liability by showcasing a commitment to responsible construction practices. Ultimately, safety signs are integral components in creating a safe, compliant, and organized construction site conducive to the well-being of all involved parties.



Figure 10-2: Safety signs for Constructional Phase

10.6 Personal Protective Equipment DURING OPERATIONAL PHASE

Personal Protective Equipment (PPE) is an essential component of the health and safety system at English Pharmaceutical Industry. It is designed to safeguard employees from

occupational hazards that may arise during pharmaceutical manufacturing, handling, and storage. PPE provides protection against:

- Chemical Hazards – Exposure to active pharmaceutical ingredients (APIs), solvents, cleaning agents, and other hazardous chemicals that may cause skin irritation, respiratory issues, or chemical burns.
- Biological Hazards – Contact with biological materials, microorganisms, or contaminated samples that can pose infection risks.
- Particulate and Dust Exposure – Protection from inhalation of pharmaceutical powders and fine particles during formulation and packaging.
- Thermal and Mechanical Hazards – Prevention of burns, cuts, or injuries from equipment, heating devices, and moving machinery.
- General Workplace Hazards – Minimization of risks from slips, trips, falls, and accidental spills.

10.7 PPE Required for English PHARMACEUTICAL industry

The use of appropriate PPE is mandatory in pharmaceutical operations to ensure a safe working environment. The following PPE is required for workers at English Pharmaceutical Industry:

- Laboratory Coats / Coveralls – To prevent contamination and protect against chemical splashes and spills.
- Gloves (Nitrile / Latex / Chemical-Resistant) – For handling chemicals, APIs, and biological materials.
- Safety Goggles / Face Shields – To protect eyes from chemical splashes, powders, or glass breakage.
- Respiratory Protection (Masks / Respirators) – For safeguarding against dust, vapors, and airborne contaminants.
- Safety Shoes / Non-Slip Footwear – To prevent injuries from slips, trips, and falling objects.

- Hearing Protection (Ear Plugs / Muffs) – Where noise levels exceed occupational safety limits.
- Head Protection (Caps / Helmets as required) – For specific operations involving overhead equipment or materials.

Regular **training, inspection, and replacement** of PPE will be ensured to maintain safety standards and regulatory compliance.



Figure 10-3: PPE required for the operational phase of English Pharmaceutical Industry

11 STAKEHOLDER CONSULTATION

Stakeholder consultation is of paramount importance in the EIA process as it facilitates inclusive decision-making, fosters transparency, and enhances the overall quality of the assessment. Involving stakeholders, including local communities, governmental bodies, non-governmental

organizations, and affected parties, ensures that diverse perspectives, concerns, and local knowledge are taken into account. This inclusive approach contributes to the identification of potential environmental and social impacts that might not be evident from a solely technical or regulatory standpoint. Stakeholder consultation is a way to involve both the primary and secondary stakeholders in making decisions about the project. Stakeholder engagement builds trust, allows for the exchange of valuable information, and empowers communities by giving them a voice in the decision-making process. Moreover, it helps to align the project with the needs and expectations of the local population, minimizing conflicts and fostering a sense of shared responsibility for environmental stewardship. In essence, stakeholder consultation transforms the EIA into a more robust and credible tool, enhancing the sustainability and social acceptance of proposed projects.

11.1 OBJECTIVES OF STAKEHOLDER CONSULTATION

In 1992, the United Nations Conference on the Environment and Development (UNCED) supported the idea of involving the public in decision-making, and this was outlined in one of the key documents of the conference called Agenda 21.

Agenda 21 is a comprehensive plan for global actions focused on sustainable development and deals with how people interact with the environment. It highlights the importance of including the public in making decisions about the environment to achieve sustainable development.

The objectives of stakeholder consultation in the context of EIA are multi-faceted, aiming to foster meaningful engagement, inclusivity, and informed decision-making. Some key objectives include:

- ✓ Ensure the inclusion of diverse stakeholder perspectives in the decision-making process, promoting a more comprehensive understanding of potential environmental and social impacts.
- ✓ Provide a platform for stakeholders to express their concerns, values, and local knowledge related to the project, contributing to a more nuanced understanding of potential impacts and benefits.
- ✓ Gather valuable insights and feedback that can be integrated into the project design, helping to address and mitigate potential adverse impacts and enhance positive contributions.

- ✓ Establish trust among stakeholders by being transparent, responsive, and open to dialogue. Building trust is essential for the successful implementation of the project and its long-term acceptance by the community.
- ✓ Fulfill regulatory requirements by actively engaging with stakeholders, demonstrating a commitment to compliance with environmental and social standards, and addressing concerns raised during the consultation process.
- ✓ Facilitate an open and inclusive dialogue to build understanding and acceptance of the project within the affected communities, minimizing potential conflicts and fostering a sense of shared responsibility.
- ✓ Integrate local knowledge and community input to enhance the overall sustainability of the project, aligning it with the needs and aspirations of the affected stakeholders.
- ✓ Disseminate accurate and accessible information about the project, its potential impacts, and proposed mitigation measures to ensure that stakeholders are well-informed and can actively participate in the decision-making process.
- ✓ Consider the needs and interests of all affected parties, including vulnerable or marginalized groups, to ensure that the benefits and burdens of the project are distributed equitably.
- ✓ Create a platform for addressing conflicts and disputes, allowing for the resolution of issues through open communication and negotiation.



Figure 11-1: Stakeholder Management

By achieving these objectives, stakeholder consultation contributes to the overall success and sustainability of the project, enhancing its social, environmental, and economic outcomes while fostering positive relationships with the communities it impacts.

11.2 PROPONENT ENVIRONMENT MANAGEMENT TEAM

A comprehensive discussion on all conceivable impacts and corresponding mitigation measures related to the project was conducted with both the proponent and project management. In this collaborative dialogue, a thorough examination of potential environmental, social, and economic implications of the project took place. The proponent and management, demonstrating a proactive commitment to responsible practices, assured the incorporation of all suggested mitigation measures to effectively control and address any discrepancies that may arise during the project's implementation. Their pledge to embrace these measures underscores a dedication to environmental stewardship and sustainable practices. By actively engaging in this discourse, the proponent and management not only exhibit a commitment to regulatory compliance but also demonstrate a broader responsibility to the well-being of the community

and the preservation of the surrounding environment. This collaborative approach ensures that the project aligns with best practices, fostering a positive impact on the environment and minimizing any potential adverse effects.

11.3 THE RESPONSIBLE AUTHORITY

The Proponent assumes the crucial role of the responsible authority, pledging to undertake all necessary measures both prior to the commencement of the project and throughout its operational phases. This commitment encompasses a comprehensive approach to project management, ensuring that all regulatory requirements, environmental standards, and best practices are diligently adhered to. Before project initiation, the Proponent commits to conducting thorough assessments and implementing necessary preparatory measures to mitigate potential impacts. This includes adopting robust environmental management strategies, obtaining required permits, and addressing any concerns raised during stakeholder consultations. Throughout the operational phase, the Proponent maintains an ongoing commitment to environmental sustainability and regulatory compliance. This involves continuous monitoring, prompt response to emerging issues, and the implementation of adaptive management practices. By assuming the mantle of responsibility, the Proponent not only safeguards the project's integrity but also prioritizes the well-being of the environment, local communities, and all stakeholders involved. This proactive stance ensures that the project operates within the parameters of environmental and ethical standards, reflecting a dedication to responsible and sustainable project execution.

Table 11-1: Stakeholders and Their Roles and Responsibilities

Stakeholders	Roles
Proponent/Responsible Authority	The discussion with the proponent proposed the mitigation measures and alternatives to control any disparity in the project.
Environmental Expert	The consultants from the Integrated Environment Consultants survey the project site to gather relevant information and to record the local community stance and behaviors regarding the project. And also the evaluation of socio-economic impacts of the project has been done.

Government Departments	The consulted government department includes Environmental protection agency, wildlife, planning, and development. The departments overviewed the proposed projects and its socio-economic impacts.
Local affected communities	The surveys determined the extent of community that could be affected and their verdict about the proposed project.

11.3.1 Other departments and agencies

A comprehensive impact analysis was conducted in collaboration with key stakeholders, including project management, the local community, educational institutes, health institutions, hospitals, and non-governmental organizations (NGOs). This inclusive approach sought to gather diverse perspectives and insights related to the implementation of the project. The engagement process involved scoping sessions, focused group discussions, and wayside consultations, providing a multifaceted platform for dialogue and information exchange. Through these forums, all pertinent issues associated with the project were thoroughly examined, including potential environmental, social, and economic impacts. The proactive involvement of stakeholders, representing various sectors of the community, ensured that a holistic understanding of the project's implications was achieved. This collaborative effort not only fostered transparency but also allowed for the incorporation of valuable local knowledge and concerns into the impact analysis. By actively engaging with stakeholders through diverse communication channels, the project management demonstrated a commitment to responsible and inclusive decision-making, setting the stage for a well-informed and socially accepted project implementation process.

11.4 ENVIRONMENTAL PRACTITIONERS AND EXPERTS

Our dedicated team undertook a comprehensive site visit, engaging in extensive discussions with a broad spectrum of project stakeholders. This inclusive approach involved reaching out to residents from nearby villages and beyond, ensuring a diverse representation of perspectives to assess the socio-economic impacts of the project. The community demographic was richly diverse, encompassing individuals from various professions, such as those employed in different fields, business owners, doctors, expatriates, military personnel, and educators. In a conscious effort to ensure gender inclusivity, consultations with women were prioritized to

gather their unique perspectives on how the project could contribute to the improvement of the area. While some women openly shared their thoughts, it was evident that social norms in the area made many feel hesitant, creating discomfort with speaking or being photographed. This nuanced understanding allowed our team to respect and navigate the cultural sensitivities of the community. The local community, nonetheless, proved to be a wellspring of information, offering valuable insights into the project and expressing predominantly positive views regarding its potential for development. This holistic approach to stakeholder engagement not only highlights the diverse fabric of the community but also underscores the importance of cultural sensitivity in ensuring meaningful and respectful interactions during the assessment of socio-economic impacts.

11.5 DISCUSSED POINTS

The points that have been kept in view while consulting stakeholders are as follows:

- ❖ Activities of the project and their consequences.
- ❖ Requirements of the people likely to be affected.
- ❖ Mitigation measures or compensation strategies.
- ❖ Role of the affected people in the implementation and development of the project.

11.6 AFFECTED AND WIDER COMMUNITY

In the vicinity of the proposed project, there is no identified affected community; however, the proactive engagement of the proponent with inhabitants from various villages has been instrumental in understanding and addressing local perspectives. The absence of a distinct affected community does not diminish the importance of comprehensive consultations. The proponent has undertaken conscientious efforts to reach out to residents across different villages, fostering a dialogue to assess the community's sentiments towards the project. Remarkably, the feedback from these consultations has been overwhelmingly positive, with residents expressing favorable views regarding the proposed endeavor. This positive reception is indicative of the proactive communication and collaborative approach adopted by the proponent, establishing a foundation of mutual understanding and support within the broader community. While the absence of an affected community streamlines certain aspects of the

engagement process, the commitment to inclusive consultations with diverse stakeholders remains integral to building a harmonious relationship with the local population.

12 Grievance Redress Mechanism

A Grievance Redress Mechanism is a structured system established to address and resolve complaints, concerns, or issues raised by individuals or entities regarding their experiences or interactions. This mechanism typically involves clear channels for lodging complaints, whether through written communication, online platforms, or dedicated grievance officers. Once a grievance is registered, the mechanism ensures a systematic and fair investigation of the matter, taking into account all relevant information and perspectives. Timely resolution and effective communication with the aggrieved party are essential components, helping to restore trust and rectify any perceived injustices. An efficient Grievance Redress Mechanism not only safeguards the rights and interests of individuals but also contributes to organizational transparency, accountability, and continuous improvement in service delivery.

12.1 OBJECTIVES OF GRIEVANCE REDRESS MECHANISM

The objectives of a GRM are designed to provide an effective and transparent process for addressing and resolving complaints or grievances raised by individuals or entities affected by a project or organization. The key objectives of a Grievance Redress Mechanism include:

- Ensure that the grievance redress process is easily accessible to all stakeholders, providing a straightforward means for individuals or communities to voice their concerns.
- Promote a fair and impartial mechanism that treats all grievances with equal consideration, regardless of the stakeholder's background, status, or affiliation.
- Establish a system that addresses grievances in a timely manner, minimizing delays and providing prompt resolution to concerns to prevent prolonged dissatisfaction.
- Foster transparency in the grievance redress process, ensuring that stakeholders are informed about the status of their complaints and the steps taken to address them.
- Hold the organization or project accountable for addressing and resolving grievances in accordance with established policies and procedures.
- Utilize the grievance redress process as an opportunity for organizational learning, collecting feedback to identify areas for improvement in project implementation or organizational practices.
- Empower affected individuals or communities by giving them a voice in the decision-making process and acknowledging the importance of their concerns.
- Serve as a mechanism for resolving conflicts and disputes in a constructive manner, minimizing the potential for escalation and promoting harmonious relationships.
- Use insights gained from the grievance redress process to enhance project design, implementation strategies, and overall organizational practices for continuous improvement.
- Ensure that the grievance redress mechanism aligns with legal requirements, industry standards, and the principles of social responsibility.
- Strengthen community engagement by demonstrating a commitment to addressing concerns and maintaining open communication channels.

By achieving these objectives, a Grievance Redress Mechanism contributes to building trust, fostering positive relationships with stakeholders, and enhancing the overall social and environmental sustainability of a project or organization.

12.2 Components of GRM

GRM typically involves several basic steps to address and resolve complaints or grievances effectively. While specific procedures may vary depending on the organization or context, the following are common steps in a basic GRM:

- Individuals submit their grievances through designated channels, which may include online platforms, written communication, or direct contact with a grievance officer.
- The received grievance is formally registered in the system, assigning a unique identifier. This step ensures proper tracking and documentation of each complaint.
- A preliminary assessment is conducted to determine the nature and severity of the grievance. This step helps in categorizing grievances and prioritizing them based on urgency.
- A thorough investigation is carried out to gather relevant information and facts related to the grievance. This may involve interviews, document reviews, or other means of inquiry.
- Clear and timely communication is maintained with the aggrieved party throughout the process. Regular updates and feedback are provided to keep them informed about the progress of the investigation.
- Once the investigation is complete, appropriate measures are taken to address the grievance. This may involve corrective actions, policy changes, compensation, or other forms of redress, depending on the nature of the complaint.
- The resolution is communicated to the aggrieved party, and feedback is sought to ensure their satisfaction. Follow-up may be conducted to confirm that the resolution has been implemented and to monitor any lingering concerns.
- The entire process, from grievance registration to resolution, is documented for record-keeping and reporting purposes. This documentation aids in analyzing trends, identifying systemic issues, and improving the overall grievance-handling process.

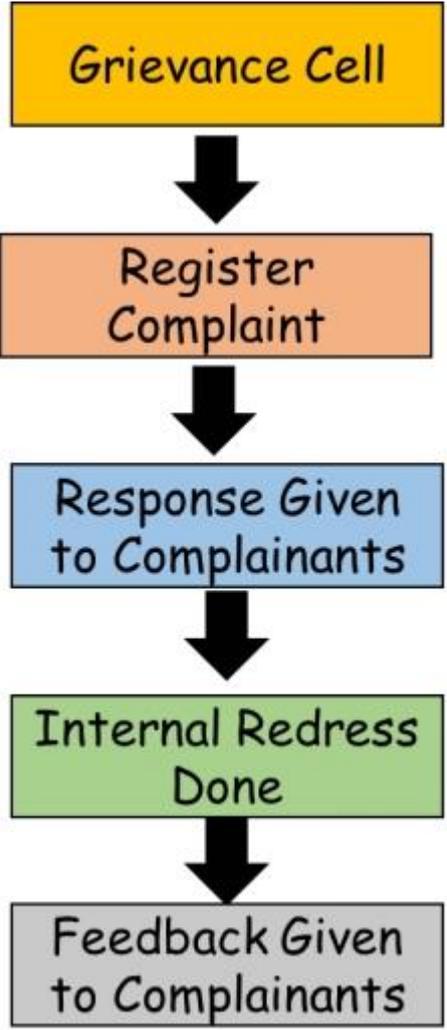


Figure 12-1: Grievance Redress Mechanism

CONCLUSION AND RECOMMENDATION

Based on the study conducted for EIA of the project, the following recommendations are made:

- ☞ Plantation as far as permissible and within the scope of the project to be carried out.
- ☞ Sustainable development approach through conservation of natural environment is followed.
- ☞ Environmental aspects of the project should be well taken care through implementation of the Environmental Management Plan as recommended in this report.
- ☞ The project management may adopt “cleaner and greener environment” as its motto and this will make the project more environment friendly.

On the basis of the findings of the EIA, it is concluded that the project will not pose any adverse impact on the local population and the environment. Therefore, it is recommended that the competent authority may please be issues Environmental Approval for the construction and operation of this project.

Glossary

Air quality	Measurement of the pollutants in the air; a description of healthiness and safety of the atmosphere.
Area	Area is the quantity that expresses the extent of a two-dimensional figure or shape, or planar lamina, in the plane.
Compensation	Includes cash payment, deferred payment, a bond, an insurance policy, stipend, payment in kind, rendition of services, grant of privileges and disturbance money, entitlement to special treatment by government and semi government entities, grant of alternative land, grant of import licenses and business, trade and commercial facilities in addition to the rehabilitation and resettlement of an affected person.
Consultation	Consultation refers to two-way transfer of information or joint discussion between project staff and the affected population. Systematic consultation implies a sustained and rigorous sharing of ideas. Bank experience shows that consultation often yields the best resettlement alternatives, fruitful procedures for continued participation, and independent information on actual conditions for implementation.
Coordinates contaminate	Each of a group of numbers used to indicate the position of a point, line, or plane to make impure, pollute
Disclosure	The action of making new or secret information known
Disruption	Disturbance or problems which interrupt an event, activity, or process.
Environmental Management	Attempt to control human impact on and interaction with the environment in order to preserve natural resources
Evaluation	The making of a judgment about the amount, number, or value of something; assessment.
Geology	A science that studies rocks, layers of soil, etc., in order to learn about the history of the earth and its life
Ground water	Aquifers currently being used as a source of drinking water or those capable of supplying a public water system. They have a total dissolved solid content of 10,000 milligrams per liter or less, and are not "exempted aquifers.
Hazardous	Substance or material, which could adversely affect the safety of the public, handlers or carriers during transportation

Impact	Effect on someone or something
Land acquisition	The process whereby a person is compelled by a public agency to cede all or part of the land a person owns or possesses, to the ownership and possession of that agency, for public purpose in return for compensation.
Mitigation	The action of reducing the severity, seriousness, or painfulness of something
Occupational health	Maintenance of the highest degree of physical, mental and social well-being of workers in all occupations by preventing departures from health, controlling risks and the adaptation of work to people, and people to their jobs
Parking	A parking garage is a building, or an area under a building, where cars can be parked.
Project area	The area specified by the funding and/or implementing agency according to the official gazette notification and includes the areas within the administrative limits of the federal or a provincial government.
Proponent	A person who advocates a theory, proposal, or course of action.
Rehabilitation	Include all compensatory measures to re-establish; at least lost incomes, livelihoods, living and social systems. It does not include the payment of compensation for required assets.
Resettlement	Means all measures taken to mitigate any and all adverse impacts, resulting due to execution of a project on the livelihood of the project affected persons, their property, and includes compensation, relocation and rehabilitation.
Scope	The extent of the area or subject matter that something deals with or to which it is relevant
Social Environment	It includes the culture that the individual was educated or lives in, and the people and institutions with whom they interact.
Stakeholders	Include affected persons and communities, proponents, private and public businesses, NGOS, host communities and EPA.

Topography

Details of the surface features of land. It includes the mountains, hills, creeks, and other bumps and lumps on a particular hunk of earth.

LIST OF ABBREVIATION

API	American Petroleum Institute
ASME	American Society of Mechanical Engineers
CO	Carbon Monoxide
CO₂	Carbon Dioxide
DCP	Dry Chemical Powder
EA	Environmental Approval
EC	Electrical Conductivity
EIA	Environmental Impact Assessment
EMMP	Environmental Management and Monitoring Plan
EMP	Environmental Management Plan
EPA	Environmental Protection and Climate Change Department
Gop	Government of Punjab
IEE	Initial Environmental Examination
IESCO	Islamabad Electric Supply Company
LPG	Liquefied Petroleum Gas
MAWP	Maximum Allowable Working Pressure
MDMT	Minimum Design Metal Temperature
NGO	Non-Governmental Organizations
P.W.H.T	Post Weld Heat Treatment
PEPA	Punjab Environmental Protection Act
PEQs	Punjab Environmental Quality Standards
PPE	Personal Protective Equipment
TDS	Total Dissolved Solid
UC	Union Council
UNCED	United Nations Conference on the Environment and Development

VOCs Volatile Organic Compounds

WAPDA Water and Power Development Authority

REFERENCES

Listed below are some of the documents, reports and other references consulted during the preparation of this report:

1. Information and data provided by project proponents;
 2. Project Pre-Feasibility Study Report;
 3. Technical Design Data related to the project.
 4. Information gathered through discussions with the project related persons of the project proponent;
 5. Information collected from the Technical documents of various suppliers of machinery/equipment.
 6. Punjab Environment Quality Standards for Ambient Air August 2016;
 7. Punjab Environment Quality Standards Noise Levels August 2016;
 8. Punjab Environment Quality Standards for Drinking Water August 2016:
 9. Pakistan Environmental Protection Act, 1997;
 10. The Punjab Environmental Protection (Amendment) Act 2012 covers aspects related to:
 - The protection, conservation, rehabilitation and improvement of the environment and the prevention, control of pollution and promotion of sustainable development;
 - Establishing complete regulatory and monitoring bodies, policies, rules, regulations and national environmental quality standards; and
 - To ensure enforcement, the act establishes regulating bodies i.e. Punjab Environmental Protection Council (PEPC) and responsible bodies i.e. Punjab Environmental Protection Agency (Punjab EPA) at Provincial level.
- i. Environment related Laws in Pakistan and the Province of Punjab;
 - ii. Government of Pakistan, Pakistan Environmental Protection Agency, Policy and Procedures for Filing, Review and Approval of Environmental Assessment, 2022;
 - iii. Google earth, maps.
 - iv. Guidelines for Public Consultations - These guidelines cover:
 - Consultation, involvement and participation of Stakeholders
 - Techniques for public consultation (principles, levels of involvements, tools, building trust)
 - Effective public consultation (planning, stages of EIA
 - where consultation is appropriate)
 - Consensus building and dispute resolution.
1. workplace safety and health act 2011
 2. Land Acquisition Act (LAA) of 1894
 3. The forest Act 1927
 4. Pakistan Penal Code, 1860
 5. Provincial Wildlife Act, 1974
 6. Drugs Act 1976

TERM OF REFERENCES

1. The Consultant is required to carry out an Environment Assessment Study of the Project as required under section 12 of Pakistan Environmental Protection Act 1997/ Punjab Environmental Protection Act 2012.
2. The Study should be comprehensive and should cover all aspects which are envisaged under the relevant national and provincial's laws & regulations including but not limited to:
 - Identification and recommendation for suitable solution/treatment/mitigation measures of emissions and effluents such as waste water and sludge etc. in accordance with Punjab Environmental Quality Standards (PEQS).
 - Identification and recommendation for suitable solution/treatment/mitigation measures of solvents, oils (tar), hazardous waste, organic compounds, steam, flue gases, particulate matter and chemical compounds harmful for the environment and other substances leading to air, noise, water and soil pollution in accordance with PEQS.

The Study should be acceptable to the relevant national and/or provincial authorities (relevant authorities) in Punjab

Annexures

ANNEXURE B

ALLOTMENT LETTER



RCCI INDUSTRIAL ESTATE RAWAT

ALLOTMENT CERTIFICATE

Serial No. 5277

Certified that



RX-7703

Mr. Anwar Habib.

H # 82/L, Block-2, PECSH, Karachi Sharki.

CNIC # 42101-4242543-5

Is here by Allotted Plot # 08 at Central Road Measuring 1200 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: renaissancecdev@yahoo.com, http:// www.renaissancecdev.org

Dated 19 July, 2023



Allotment Conditions

1. Payment including surcharge for the late remission of installment / dues 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.

