Environmental Impact Assessment (EIA) on ***"Expansion of API Manufacturing Unit (Bulk Drugs)."***

Client: ABC Pharma Synthetics.

Project Location: Industrial Zone (Riverine Ecosystem Context)

Lead Consultant: Mr. XYZ

Date of Submission: [xx/xx/xxxx]

Background: ABC Pharma Synthetics is planning the expansion of an existing chemical plant to produce Active Pharmaceutical Ingredients (APIs) involving bulk solvents and reactors. An EIA is needed to analyze the Zero Liquid Discharge (ZLD) system efficiency, to assess the risk of hazardous chemical spills and emergency response plans, to measure the baseline air quality (VOCs) and predict the increase in pollutant load, and to obtain the "Consent to Establish" (CTE) and "Consent to Operate" (CTO) from regulatory bodies.

Prepared by: Temkars Agri-Tech & Geospatial Consultancy

, Pune

Email: contact@temkars.in Contact: +91 9028541024 www.temkars.in

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1.0 Executive Summary

Project Overview:

ABC Pharma Synthetics proposes the expansion of its existing Active Pharmaceutical Ingredient (API) manufacturing unit located in the Industrial Zone, adjacent to a river that serves as a critical drinking water source for downstream communities. The expansion aims to increase production capacity by [insert MT/month] and introduce the following APIs:

S. No	API Name	Projected Capacity (MT/month)	Reactor Type
1	Amoxicillin	XX	Batch Reactor
2	Atenolol	XX	Continuous Stirred Tank Reactor (CSTR)
3	Metformin Hydrochloride	XX	Batch Reactor
4	Ciprofloxacin	XX	CSTR + Filtration Unit

Note: Exact capacities are project confidential; values in final report will be as per client data.

Critical Environmental Sensitivities:

- Proximity to River: The river downstream serves as a potable water source. Any effluent discharge or chemical spillage could have serious implications for human health and aquatic ecology.
- Handling of Bulk Solvents: Organic solvents (Methanol, Toluene, Acetone, etc.) present risks of air emission, flammability, and accidental release.

Key Environmental Commitments:

1. Zero Liquid Discharge (ZLD): Full treatment of all process effluents to prevent any discharge to surface water, with recovery of >95% solvents.
2. Leak Detection and Containment: Installation of vent condensers, scrubbers, activated carbon filters, and continuous VOC monitoring to ensure workplace safety and minimal ambient emissions.
3. Hazardous Waste Management: All process residues, sludge, and spent catalysts will be disposed of at approved TSDFs or co-processed in cement kilns.
4. Green Belt Development: 33% of total plant area allocated to dense plantation to act as a bio-shield and reduce ambient odor/chemical exposure.

Regulatory Status:

- The project falls under the Red Category (high pollution potential) industry as per the Ministry of Environment, Forest and Climate Change (MoEFCC) Notification, Schedule 5(f) - Synthetic Organic Chemicals (EIA Notification, 2006).
- Consent to Establish (CTE) and Consent to Operate (CTO) will be obtained from the State Pollution Control Board (SPCB) upon successful implementation of mitigation measures.
- Public hearings will be conducted in downstream communities to address stakeholder concerns regarding water quality, air emissions, and emergency preparedness (MoEFCC, 2023; CPCB, 2022).

Outcome of the EIA:

The EIA evaluates potential impacts on water, air, soil, and human health, providing a quantitative risk assessment (QRA) for accidental releases. If mitigation measures are strictly implemented—particularly the ZLD system, VOC control, and emergency response—the project is environmentally viable.

Conclusion:

The project presents significant healthcare and economic benefits, including:

- Ensuring domestic API production to reduce import dependency.
- Employment generation for skilled technicians and chemists.
- Corporate Social Responsibility initiatives, including funding of local water purification systems.

Recommendation:

- Approval of EC (Environmental Clearance) is conditional upon strict ZLD adherence, continuous VOC monitoring, and installation of spill response protocols connected to SPCB emergency systems.
- Regular third-party audits and reporting to regulatory authorities are recommended to ensure compliance.

2.0 Introduction

2.1 Background

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