IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 6, November 2025
Impact Factor: 7.67

Analysis of Environmental Impact Assessment (EIA) of Pharmaceutical Industry Expansion in Gujarat: A Critical Review of Challenges, Key Impacts, and Pathways to Sustainability

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Abstract: *The pharmaceutical sector in Gujarat particularly in hubs like Ahmedabad, Vadodara, Ankleshwar, Surat and Vapi—has expanded significantly over the past two decades. While this growth strengthens India's global position in drug manufacturing, it also raises environmental sustainability concerns. Environmental Impact Assessment (EIA) serves as a critical regulatory tool to identify, predict, and mitigate environmental impacts of new pharmaceutical units and their expansions. This paper analyzes the effectiveness of EIA processes in Gujarat's pharmaceutical industry, identifies major challenges and environmental impacts, evaluates the regulatory and implementation gaps, and proposes sustainable pathways to improve compliance and environmental performance.*

Keywords*:* Environmental Impact Assessment, Pharmaceutical Industry, Gujarat, India, Environmental Pollution, Sustainability, Industrial Expansion, Green Technology

I. INTRODUCTION

The pharmaceutical industry plays a critical role in global health by providing essential medicines. However, pharmaceutical manufacturing is resource-intensive and environmentally burdensome: the processes often consume large quantities of water and energy, produce toxic chemical waste, and generate emissions that threaten ecosystems and human health.As countries aim for industrial growth including expansion of pharmaceutical plants it becomes increasingly important to assess the environmental consequences before project approval. The process widely used for this is the Environmental Impact Assessment (EIA), which evaluates potential environmental effects of proposed projects and prescribes mitigation measures.

Gujarat contributes nearly 33% to India's pharmaceutical turnover and 28% of exports, making it the country's largest pharmaceutical hub. The rapid expansion of drug formulation plants, bulk drug units, and API manufacturing facilities has created significant environmental concerns including water contamination, hazardous waste, solvent emissions, and land degradation.

Environmental Impact Assessment (EIA) is a statutory process intended to predict, evaluate, and mitigate environmental impacts prior to project approval. Under the EIA Notification (2006), pharmaceutical units fall under Category below depending on their production capacity. This paper critically examines the effectiveness of EIA in ensuring environmentally responsible pharmaceutical development in Gujarat.

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Conceptual Framework

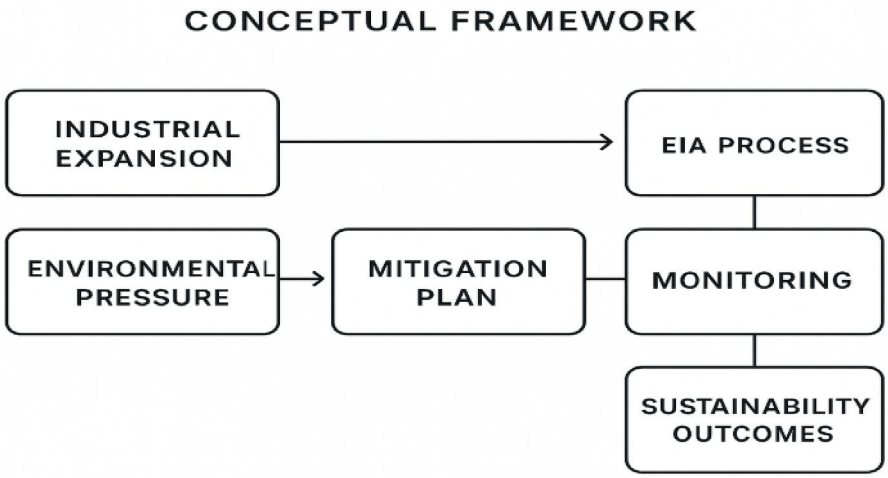

Fig.1. Conceptual Framework on EIA of Pharmaceutical Industry Expansion

This research examines how EIA is applied (or should be applied) for pharmaceutical-industry expansion, what the major environmental impacts are, how effectively EIA (and subsequent environmental management) addresses these impacts, and what strategies exist to reduce the environmental footprint of the industry in a sustainable manner.

II. BACKGROUND, SIGNIFICANCE AND METHODOLOGY

The global pharmaceutical industry is experiencing rapid growth, driven by increasing populations, life expectancy, and medical advancements. This expansion necessitates the construction of new facilities and the scaling up of existing manufacturing units. While economically beneficial, the production of drugs, especially the synthesis of Active Pharmaceutical Ingredients (APIs), is chemically intensive and recognized as highly polluting. Studies have indicated that the pharmaceutical production process can have a significantly high emission intensity compared to other sectors.

Pharmaceutical Industry Landscape in Gujarat

Gujarat hosts more than 40% of India's pharmaceutical production units, concentrated in Ahmedabad, Vadodara, Vapi, and Ankleshwar [2]. These clusters are known for drug formulations, bulk drug production, and chemical intermediates.

Environmental Impact Assessment (EIA) Process

The EIA process comprises:

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- Screening
- Scoping
- Baseline environmental data collection
- Impact prediction
- Public consultation
- Environmental Management Plan (EMP)
- Monitoring and compliance

Importance of EIA in Pharmaceutical Sector

Pharmaceutical manufacturing involves complex chemicals, high-strength effluents, volatile organic compounds (VOCs), and hazardous waste. Effective EIA is essential for managing these environmental risks.

Scope of the Study

This study focuses on evaluating the Environmental Impact Assessment (EIA) process as it applies to the expansion of the pharmaceutical industry. The scope encompasses both **regulatory frameworks** and **environmental consequences** associated with establishing or enlarging pharmaceutical manufacturing units. It includes an examination of:

- **Key environmental impacts** generated by pharmaceutical industry expansion, including chemical waste, wastewater, air emissions, water consumption, energy use, and ecological disturbances.
- **EIA methodologies and procedures** used to assess these impacts, including baseline studies, impact prediction, mitigation planning, and public consultation.
- **Effectiveness of the EIA process**, including its strengths, limitations, compliance mechanisms, and enforcement in the context of industrial expansion.
- **Case-based or literature-based assessments** of how pharmaceutical projects have been evaluated through EIAs in different regions, with emphasis on developing countries.
- **Sustainable alternatives and mitigation strategies**, such as green chemistry, advanced effluent treatment, and energy-efficient production processes.
- **Policy and management implications**, covering regulatory gaps, monitoring needs, and the role of environmental management plans (EMP) after EIA approval.

The study does **not** focus on clinical trials, drug safety/efficacy, market dynamics, or supply-chain logistics except where they affect environmental compliance. Nor does it address pharmaceutical waste generated by consumers (post-use) unless relevant to EIA considerations.

Objectives of the Study

The primary aim of this research is to provide a comprehensive assessment of how effectively the Environmental Impact Assessment (EIA) framework addresses the environmental challenges posed by the expansion of the pharmaceutical industry. The specific objectives are:

- To identify and analyze the major environmental impacts associated with pharmaceutical industry expansion, including emissions, effluents, solid waste, resource consumption, and long-term ecological risks.
- To assess the adequacy and effectiveness of existing EIA procedures in evaluating these impacts, including the depth of baseline studies, prediction techniques, risk analysis, and proposed mitigation measures.
- To evaluate the regulatory landscapeby examining laws, guidelines, and compliance mechanisms governing pharmaceutical industry EIAs at national and regional levels.
- To highlight gaps, limitations, and challengesin the current EIA framework,especially regarding emerging contaminants such as persistent pharmaceutical residues and APIs.
- To examine case studies or documented examplesof EIAs conducted for pharmaceutical expansion projects, identifying lessons learned and areas for improvement.

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- To propose strategies for strengthening the EIA processthrough improved monitoring, lifecycle-based assessment, advanced treatment technologies, sustainability metrics, and green manufacturing practices.
- To recommend policy and operational improvementsfor ensuring that pharmaceutical industry expansion balances economic benefits with long-term environmental protection and public health.

Methodology

This research uses:

- A review of EIA reports and clearance documents from MoEFCC and GPCB.
- Analysis of scientific literature, CPCB guidelines, and WHO/UNEP reports.
- Evaluation of EIA quality parameters (baseline data, modeling, EMP adequacy).
- Comparative case evaluation of Vapi, Ankleshwar, and Ahmedabad clusters.

III. LITERATURE REVIEW

Environmental Impact Assessment (EIA) is a key regulatory instrument for predicting, evaluating, and mitigating adverse environmental impacts of industrial activities. The pharmaceutical industry, owing to its complex chemical processes and hazardous waste generation, has been a subject of growing academic and regulatory concern. This literature review synthesizes relevant studies from India and global contexts, with emphasis on Gujarat, examining EIA processes, pharmaceutical pollution, regulatory challenges, and sustainability frameworks.

Glasson et al. (2005) discussed EIA as a critical environmental management tool, highlighting its role in balancing industrial development with ecological protection. They emphasized the need for strong scoping, public participation, and post-clearance monitoring—areas that remain weak in Gujarat's EIA process.

Morris and Therivel (2009) further illustrated that EIAs often suffer from inadequate baseline data and overdependence on consultants, consistent with critiques of Indian EIA reports.

According to Rajaram and Das (2011), the Indian EIA framework faces issues such as poor-quality reports, limited stakeholder involvement, and insufficient monitoring. These insights align with observations from MoEFCC reviews of industrial EIAs in Gujarat.

Kohli and Menon (2016) evaluated the effectiveness of India's EIA Notification 2006, arguing that procedural loopholes and increased exemptions have weakened regulatory oversight, especially in rapidly industrializing regions like Gujarat.

Gujarat Pollution Control Board (GPCB, 2021) reports indicate high levels of chemical pollution in districts like Bharuch, Ankleshwar, and Vapi. Environmental monitoring data have shown cumulative contamination of rivers and groundwater, emphasizing the need for more rigorous EIAs prior to industrial expansion.

Shah and Patel (2020) studied Gujarat's pharmaceutical clusters and found widespread issues in hazardous waste disposal, suggesting that EIAs often underestimate long-term impacts.

Larsson (2014) highlighted that pharmaceutical effluents contain active pharmaceutical ingredients (APIs), solvents, and antibiotics that contribute to antimicrobial resistance (AMR). This underscores a major gap in Indian EIAs, which generally omit AMR risk assessments.

Fatta-Kassinos et al. (2011) showed that pharmaceutical wastewater often contains persistent organic pollutants, necessitating advanced treatment technologies that are not consistently adopted in Gujarat.

Mutiyar and Mittal (2014), In a study focused on Indian pharma clusters, documented high concentrations of antibiotics in effluents, indicating ineffective ETP and CETP operations.

CPCB's Comprehensive Environmental Assessment (CEPI) reports (2009–2020) identified Vapi and Ankleshwar as some of the most polluted industrial regions due to extensive chemical and pharmaceutical activity. The reports documented poor CETP performance and inadequate EIA compliance.

Suthar et al. (2019) assessed groundwater near Ankleshwar and found elevated TDS, heavy metals, and pharmaceutical residues. The study revealed that EIAs failed to project cumulative pollution load from the cluster.

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Paliwal (2006) evaluated the quality of Indian EIA reports, concluding that many suffer from copy-paste practices, insufficient impact prediction, and weak mitigation plans—issues echoed in analyses of pharmaceutical EIAs submitted in Gujarat.

Khoshoo (2017) argued that consultant-driven EIAs often prioritize project clearance over environmental integrity, urging stricter accreditation and monitoring.

Menon and Kohli (2018) highlighted structural issues with India's public hearing process, including inadequate information dissemination, limited community engagement, and tokenistic consultations. These findings mirror common critiques in Gujarat's industrial public hearings.

Studies by Kumar and Prakash (2020) showed that local communities near Gujarat's pharma hubs often face health risks but have limited voice in EIA processes.

Narain and Bell (2016) emphasized that Indian pollution control boards face severe manpower and resource shortages, limiting their ability to enforce EIA conditions. This is highly relevant in Gujarat, where rapid industrialization outpaces regulatory capacity.

Hussain et al. (2019) analyzed post-clearance compliance and found that industries often underreport emissions, with weak enforcement mechanisms.

Gupta and Singh (2017) documented that adoption of green chemistry reduces solvent waste and emissions. However, adoption remains limited in Indian bulk drug units.

Studies by UNEP (2019) and WHO (2018) proposed frameworks for sustainable pharmaceutical waste management, highlighting the importance of Zero Liquid Discharge (ZLD), advanced oxidation processes, and circular economy approaches—practices increasingly encouraged in Gujarat's SEZs.

Nema and Modak (2008) emphasized the necessity of cumulative impact assessment for industrial clusters—a requirement often missing in Gujarat, where pharmaceutical industries function within dense chemical belts.

CPCB (2015) reports recommended CIA for critically polluted industrial areas to better assess long-term environmental implications.

Summary of Literature Insights

Theme	Key Insights
Strength of EIA Framework	Strong structure but weak implementation in India and Gujarat
Data Quality Issues	Poor-quality reports, copy-paste data, inadequate seasonal data
Environmental Impacts	Water pollution, API residues, hazardous waste, AMR development
Regulatory Gaps	Weak monitoring, limited human resources, inadequate post-clearance audits
Public Engagement	Low awareness, limited transparency in public hearings
Sustainable Pathways	Green chemistry, digital monitoring, ZLD, circular waste management

Overall, the literature clearly indicates that while pharmaceutical EIAs in Gujarat followstatutory requirements, their quality, monitoring, and long-term impact assessment remain inadequate. There is strong academic support for technologically advanced waste-treatment systems, better regulatory oversight, cumulative impact analysis, and enhanced community participation.

IV. ENVIRONMENTAL CHALLENGES AND CRITICAL REVIEW OF PHARMACEUTICAL INDUSTRY IN GUJARAT

Water Pollution:- Pharmaceutical effluents contain high Total Dissolved Solids (TDS), Chemical Oxygen Demand (COD), Biochemical Oxygen Demand (BOD), antibiotics, and toxic intermediates. Improper discharge affects Sabarmati River and groundwater sources in Vapi and Ankleshwar.

Air Pollution:- Major air pollutants include VOCs, SOx, NOx, particulate matter, ammonia, and solvent vapors. Air dispersion models often underestimate impacts due to limited baseline data.

Solid and Hazardous Waste

Pharmaceutical units generate:

solvent residues

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sludge
API-contaminated waste
expired drug waste
Improper disposal creates toxic hotspots and land contamination.

Impact on Ecosystems: -Effluent-laden water impacts aquatic ecosystems, while land-use changes alter terrestrial biodiversity.

Critical Review of EIA Practices in Gujarat

A. Procedural Gaps

- *Incomplete baseline studies*: Many EIA reports lack multi-seasonal data, making predictions unreliable.
- *Outdated methodologies*: Modeling tools such as ISCST3 are used instead of AERMOD or advanced water models.
- *Copy-paste reporting*: Several EIAs contain generic templates without site-specific analysis.

B. Regulatory Weaknesses

- Limited manpower in GPCB hampers monitoring.
- Post-clearance compliance is poorly enforced.
- Insufficient laboratory infrastructure reduces monitoring accuracy.

C. Public Participation Issues

- Public hearings are often procedural rather than meaningful:
- Community members lack technical knowledge.
- Limited access to EIA reports.
- Concerns about pollution often not incorporated into final EMP.

D. Case Study Summary

Cluster	Key Issues	Identified EIA Gaps
Vapi	High effluent toxicity	Weak CETP monitoring
Ankleshwar	Hazardous chemical waste	Inadequate baseline data
Ahmedabad	Solvent emissions	Poor air modeling

Key Environmental Impacts Observed

A. Human Health

Exposure to pharmaceutical pollutants leads to:
respiratory illnesses
skin irritation
chronic health conditions due to long-term chemical exposure

B. Water Resources

Untreated wastewater leads to:
groundwater contamination
higher treatment costs
reduction in agricultural productivity

C. Socio-Economic Impacts

While industrial growth increases employment, it also:
strains local infrastructure

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generates community conflicts
reduces environmental quality affecting agriculture and fisheries

V. PATHWAYS TO SUSTAINABILITY

A. Improving EIA Quality

- Adoption of advanced modeling tools (AERMOD, QUAL2K).
- Multi-seasonal baseline monitoring.
- Independent third-party EIA reviews.

B. Adoption of Green Chemistry

- Use of cleaner solvents.
- Reduction in hazardous intermediate processes.
- Adoption of Zero Liquid Discharge (ZLD).

C. Digital Environmental Monitoring

- IoT-based Continuous Emission Monitoring Systems (CEMS).
- Blockchain-based hazardous waste tracking.
- Real-time data sharing with regulatory authorities.

D. Strengthening Waste Management

- Solvent recovery units.
- Circular economy–based waste minimization.
- Scientific disposal of expired drugs.

E. Enhancing Public Participation

- Online accessible EIA summaries.
- Enhanced community awareness.
- Regular social audits.

F. Policy and Institutional Strengthening

- Stronger enforcement by GPCB.
- Annual environmental audits.
- Integration of ESG reporting for industries.

VI. CONCLUSION

The expansion of the pharmaceutical industry in Gujarat has strengthened the state's economic profile but has also intensified environmental challenges. This review reveals significant gaps in the EIA process, including weak baseline data, insufficient public participation, outdated modeling approaches, and limited enforcement. Strengthening the EIA ecosystem through digital monitoring, green chemistry, improved transparency, and robust regulatory frameworks is essential to achieve long-term sustainability. Gujarat can become a global model for sustainable pharmaceutical development if environmental safeguards are integrated into industrial growth strategies.

A multi-dimensional strategy—anchored in technological modernization, regulatory strengthening, scientific assessment, and social transparency—is essential to align Gujarat's pharmaceutical expansion with environmental sustainability. With robust reforms, Gujarat can emerge as a model for sustainable pharmaceutical manufacturing, balancing economic growth with ecological responsibility.

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