



API DISCHARGE MANAGEMENT POLICY

Office: 25/2, Main Mathura Road, Village Kaili, Ballabhgarh, Faridabad, Haryana 121004

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1. INTRODUCTION

Alchem International Private Limited is committed to minimizing the environmental impact of its manufacturing operations. As one of the leading manufacturers of Active Pharmaceutical Ingredients (APIs), botanical extracts, phytochemicals, and nutraceutical ingredients, we recognize our responsibility to protect the environment and public health by managing and controlling the discharge of APIs into the environment. This policy outlines our principles, engagements, qualitative objectives, and quantitative targets to address API-related issues across all our manufacturing facilities.

Alchem International acknowledges that APIs—including Digoxin, Atropine, Hyoscine Butyl Bromide, Colchicine, and Paclitaxel—are biologically active compounds that can adversely affect aquatic ecosystems, contaminate drinking water sources, and contribute to antimicrobial resistance if released into the environment. Therefore, we are committed to preventing, minimizing, and controlling API discharges through advanced treatment technologies, robust process controls, and continuous monitoring.

This policy is aligned with:

- The **Environment Protection Act, 1986**
- The **Water Act, 1974**
- **CPCB/SPCB Guidelines** for pharmaceutical industry effluent
- The **Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016**
- The **Stockholm Convention** on Persistent Organic Pollutants
- **Customer requirements** for API discharge management
- **AMR Industry Alliance** framework and **PSCI** principles
- **ISO 14001** Environmental Management Systems

2. SCOPE

This policy applies to all manufacturing operations at Alchem International Private Limited, including all employees, contractors, workers, and suppliers involved in the production,



handling, and disposal of APIs, botanical extracts, phytochemicals, and nutraceutical ingredients.

It encompasses all stages of the manufacturing process where API discharges might occur, including:

- Botanical raw material handling and processing
- Extraction, isolation, and purification operations
- Synthesis and semi-synthesis operations
- Quality control and analytical laboratories
- Research and development laboratories
- Pilot plant and scale-up operations
- Effluent Treatment Plant (ETP) and wastewater treatment systems
- Utilities and equipment cleaning areas
- Warehouse and raw material storage areas
- Packing and finishing operations

This policy applies to all Alchem International locations, including the manufacturing facility at 25/2, Main Mathura Road, Village Kaili, Ballabhgarh, Faridabad, Haryana 121004, and any future sites.

3. PRINCIPLES

This policy is guided by the following principles:

Principle	Description
Compliance	Adhering to all applicable local, national, and international environmental regulations and standards regarding API discharges, including CPCB/SPCB norms, Environment Protection Act, 1986, and Water Act, 1974.
Prevention	Implementing proactive measures to prevent or minimize the release of APIs into the environment through source-level controls, process optimization, and advanced treatment technologies.
Sustainability	Promoting sustainable practices in our manufacturing processes to reduce environmental impacts, conserve resources, and support circular economy principles.
Transparency	Maintaining open communication with stakeholders regarding our environmental performance and API discharge management through regular reporting and disclosure.



Continuous Improvement	Regularly reviewing and improving our processes and practices to enhance environmental performance, adopt emerging technologies, and achieve progressive reduction targets.
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4. ENGAGEMENTS

Alchem International Private Limited is committed to:

4.1 Stakeholder Engagement

Engaging with regulatory bodies, local communities, customers, and industry partners to promote transparency and accountability. This includes:

- Regular communication with CPCB/SPCB and local authorities
- Community engagement on environmental performance
- Customer collaboration on API discharge requirements
- Participation in industry associations and initiatives (AMR Industry Alliance, PSCI)

4.2 Training and Awareness

Providing regular training to employees and contractors on best practices for managing API discharges and raising awareness about environmental protection. This includes:

- Induction training on API discharge prevention
- Annual refresher training on environmental management
- Specialized training on wastewater treatment technologies
- Awareness programmes on pharmaceutical waste in the environment

4.3 Research and Development

Investing in research and development to find innovative solutions for minimizing API discharges and improving environmental sustainability. This includes:

- Evaluation of advanced oxidation processes (AOPs)
- Membrane filtration technology assessment (NF, RO)
- Green chemistry and process intensification
- Solvent recovery and reuse technologies
- Pilot studies on emerging treatment technologies



5. QUALITATIVE OBJECTIVES

Our Qualitative Objectives include:

Objective	Description
Enhancing Process Efficiency	Continuously improving manufacturing processes to reduce the generation of API waste through yield improvement, process optimization, and solvent recovery.
Strengthening Controls	Implementing robust control measures to prevent accidental releases of APIs through secondary containment, spill prevention, and emergency response preparedness.
Promoting Best Practices	Adopting and promoting industry best practices for environmental management and API discharge control, including AMR Industry Alliance and PSCI frameworks.
Ensuring Compliance	Maintaining full compliance with all regulatory requirements related to API discharges, including CPCB/SPCB norms, customer requirements, and international standards.
Advancing Treatment Technologies	Implementing advanced treatment technologies—including Advanced Oxidation Processes (AOPs), membrane filtration (nanofiltration, reverse osmosis), and activated carbon adsorption—for effective API removal.
Protecting Aquatic Ecosystems	Preventing contamination of surface water, groundwater, and soil from pharmaceutical compounds through responsible discharge management.

6. QUANTITATIVE TARGETS

To measure our progress and effectiveness, we have established the following Quantitative Targets:

Target	Description	Baseline	Target Year
Reduction of API Discharges	Maintain a record of Zero API discharge into the environment to the extent achievable through advanced treatment.	FY 2023-24	FY 2030-31
Emission Control	Ensure that 100% of emission points have effective control technologies installed and operational.	FY 2023-24	FY 2030-31
API Discharge Limit Compliance	Target 100% compliance of API discharge limit for final outlet of Effluent Treatment Plant (ETP) (Not more than 0.05 mg/L as per CPCB guidelines and MOEF notification).	FY 2023-24	FY 2030-31



Take-Back of Expired APIs	Ensure 100% take-back of Expired Active Pharmaceutical Ingredients (API) as per the Product Recall Procedure.	FY 2023-24	FY 2030-31
Water Recycling	Achieve 50% water recycling and reuse in manufacturing operations.	FY 2023-24	FY 2030-31
Solvent Recovery	Achieve 90% solvent recovery and reuse in extraction and purification operations.	FY 2023-24	FY 2030-31
Treatment Efficiency	Achieve 95% API removal efficiency across all treatment systems.	FY 2023-24	FY 2030-31
Monitoring Compliance	Achieve 100% compliance with API monitoring and reporting requirements.	FY 2023-24	FY 2030-31

7. RESPONSIBILITY

Effective implementation of the API Discharge Management Policy requires clear delineation of responsibilities across various roles within Alchem International Private Limited. The following sections outline the detailed responsibilities for each key role involved.

7.1 Management

Responsibilities:

Responsibility	Description
Resource Allocation	Ensure adequate resources (financial, human, and technical) are allocated to implement and maintain this policy effectively.
Policy Oversight	Oversee the implementation of the Policy, ensuring it aligns with the Company's strategic objectives and regulatory requirements.
Leadership	Foster a culture of environmental responsibility and sustainability within the organization.
Performance Review	Regularly review environmental performance reports and ensure corrective actions are taken when necessary.
Engagement	Engage with external stakeholders, including regulatory bodies, industry associations, and the community, to promote transparency and collaboration.
Target Setting	Approve quantitative targets and monitor progress toward FY 2030-31 goals.



7.2 Environmental Health and Safety (EHS) Team

Responsibilities:

Responsibility	Description
Procedure Development	Develop, implement, and maintain procedures for managing API discharges, ensuring compliance with environmental regulations.
Monitoring and Reporting	Conduct regular monitoring of API discharges, maintain accurate records, and report findings to management and regulatory authorities.
Risk Assessment	Perform risk assessments to identify potential sources of API discharges and develop mitigation strategies.
Incident Management	Manage and investigate incidents of API discharges, ensuring prompt corrective actions and reporting to relevant authorities.
Training Coordination	Organize and conduct training programs for employees and contractors on best practices for managing API discharges.
Audits and Inspections	Conduct regular environmental audits and inspections to ensure compliance with the policy and identify areas for improvements.
Technology Evaluation	Evaluate and recommend advanced treatment technologies (AOPs, membrane filtration, activated carbon) for API removal.
Regulatory Liaison	Maintain communication with CPCB/SPCB and other regulatory authorities.

7.3 Production Staff

Responsibilities:

Responsibility	Description
Compliance	Adhere to established procedures for preventing and controlling API discharges during manufacturing operations.
Incident Reporting	Immediately report any incidents or potential risks of API discharges to the EHS team or management.
Participation in Training	Actively participate in training programs and stay updated on best practices and regulatory requirements related to API discharges.
Process Improvement	Provide feedback and suggestions for improving processes and practices to minimize API discharges.
Source Segregation	Segregate high-strength API-containing waste streams at source for separate treatment.
Spill Prevention	Follow spill prevention procedures and respond promptly to spills.



7.4 Quality Control and Assurance

Responsibilities:

Responsibility	Description
Quality Monitoring	Ensure that all products and processes meet quality standards that also align with environmental regulations for API discharges.
Testing and Analysis	Conduct rigorous testing and analysis of API levels in waste streams and emissions to ensure they meet regulatory standards.
Documentation	Maintain detailed records of quality control tests and environmental compliance data.
Process Improvement	Provide feedback and suggestions for improving processes and practices to minimize API discharges.
Analytical Method Development	Develop and validate analytical methods for API detection in wastewater (HPLC, LC-MS/MS, GC-MS).
Sampling Protocol	Implement and maintain sampling protocols for API monitoring.

7.5 Maintenance Team

Responsibilities:

Responsibility	Description
Equipment Maintenance	Ensure that all emission control and waste management equipment is properly maintained and functioning efficiently.
Preventive Maintenance	Conduct regular preventive maintenance to prevent equipment failures that could lead to unintended API discharges.
Record Keeping	Maintain detailed maintenance records and promptly address any issues identified during routine inspections.
Backup Systems	Ensure backup equipment (pumps, treatment units) is available and operational for emergency response.
Calibration	Ensure calibration of monitoring instruments and treatment system controls.



7.6 Research and Development (R&D) Team

Responsibilities:

Responsibility	Description
Innovation	Research and develop new methods and technologies to reduce API discharges and improve environmental sustainability.
Process Optimization	Work on optimizing manufacturing processes to minimize waste and emissions.
Collaboration	Collaborate with the EHS team to implement new technologies and process improvements effectively.
Green Chemistry	Evaluate green chemistry alternatives and safer chemical substitutions.
Pilot Studies	Conduct pilot studies on emerging treatment technologies for API removal.
Technology Transfer	Support scale-up and technology transfer of successful pilot studies.

7.7 Suppliers and Contractors

Responsibilities:

Responsibility	Description
Compliance	Comply with Alchem International Private Limited's environmental standards and procedures regarding API discharges.
Training	Participate in training provided by Alchem International Private Limited on environmental management and API discharge control.
Reporting	Report any incidents or potential risks of API discharges immediately to the relevant contact at Alchem International Private Limited.
Sustainable Practices	Implement sustainable practices in their operations to minimize the environmental impact of their activities related to Alchem International Private Limited.
Due Diligence	Support Alchem International's third-party due diligence processes.

7.8 Employees

Responsibilities:

Responsibility	Description
Awareness	Be aware of the environmental policy and understand their role in minimizing API discharges.



Best Practices	Follow best practices for environmental management and participate in training programs.
Incident Reporting	Report any potential or actual API discharges or environmental concerns to their supervisor or EHS team.
Continuous Improvement	Provide suggestions for improving environmental performance.
Compliance	Follow all applicable procedures and regulatory requirements.

8. PROCEDURE

8.1 Prevention and Control

Measure	Description
Process Design	Incorporate API discharge minimization strategies in the design and operation of manufacturing processes, including yield improvement, solvent recovery, and process intensification.
Waste Management	Implement waste management practices to ensure proper handling, treatment, and disposal of API-containing waste, including segregation of high-strength streams, hazardous waste management, and authorized disposal.
Emission Control	Use advanced emission control technologies to capture and treat airborne API discharges, including scrubbers, biofilters, activated carbon adsorption, and thermal oxidisers.
Source Segregation	Segregate high-strength API-containing waste streams at source to prevent mixing with general effluent and enable targeted treatment.
Secondary Containment	Provide secondary containment for chemical storage and handling areas to prevent accidental releases.
Spill Prevention	Implement spill prevention measures and maintain spill kits at strategic locations for immediate response.
Equipment Maintenance	Maintain equipment to prevent leaks, spills, and unintended releases.
Operator Training	Train operators on safe handling, spill prevention, and emergency response.

8.2 Treatment Technologies for API Removal

Alchem International employs a multi-barrier treatment approach for API removal, combining multiple technologies to achieve effective removal of pharmaceutical compounds.

Technology	Description	Application
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Advanced Oxidation Processes (AOPs)	Chemical treatment generating hydroxyl radicals for API degradation. Types include Fenton, Ozone-based, UV/H ₂ O ₂ , Photocatalytic, Electrochemical, and Wet Air Oxidation.	High-strength API waste streams
Membrane Filtration (NF, RO)	Physical separation based on molecular size and charge. Types include Reverse Osmosis, Nanofiltration, Ultrafiltration, Microfiltration, Forward Osmosis, and Membrane Bioreactor.	Process wastewater, polishing
Activated Carbon Adsorption	Adsorption of organic compounds including APIs. Types include Granular Activated Carbon (GAC), Powdered Activated Carbon (PAC), and Biological Activated Carbon (BAC).	Low-concentration API streams
Biological Treatment Enhancement	Acclimation, nutrient supplementation, bioaugmentation, co-metabolism, extended SRT.	Secondary treatment
Integrated Treatment Train	Combination of multiple technologies for comprehensive API removal.	Full-scale treatment

8.3 Integrated Treatment Train

Treatment Stage	Technology	Purpose
Pre-treatment	Screening, equalisation, pH adjustment	Remove solids, homogenise flow, optimise pH
Primary Treatment	Chemical coagulation, sedimentation	Remove suspended solids, some APIs
Secondary Treatment	Activated sludge, MBR	Biological degradation of APIs
Tertiary Treatment	AOPs, membrane filtration, activated carbon	Advanced removal of recalcitrant APIs
Polishing	UV disinfection, final filtration	Final polishing before discharge/reuse
Sludge Treatment	Dewatering, drying, disposal	Manage treatment residuals



8.4 Monitoring and Reporting

Activity	Description	Frequency
Regular Monitoring	Conduct regular monitoring of API discharges at all relevant points in the manufacturing process, including individual process streams, combined effluent, and treated effluent.	Daily / Weekly / Monthly (based on API priority)
Reporting	Maintain accurate records of API discharge levels and report findings to regulatory authorities as required.	Monthly / Quarterly / Annually
Incident Reporting	Report any incidents of API discharges immediately to EHS and management. Use advanced emission control technologies to capture and treat airborne API discharges.	Immediate
Regulatory Reporting	Submit reports to CPCB/SPCB and other authorities as required.	As per regulation
Customer Reporting	Provide API discharge reports to customers as per contractual requirements.	As per contract
Internal Reporting	Report monitoring data to management for review.	Monthly

8.5 API Discharge Limits and Monitoring

API Category	Internal Limit (mg/L)	Regulatory Limit (mg/L)	Monitoring Frequency
High Priority APIs	0.01	0.1	Daily
Medium Priority APIs	0.1	1.0	Weekly
Low Priority APIs	1.0	10.0	Monthly
Total API Load	5.0	50.0	Daily

8.6 Documentation and Recordkeeping

Alchem International maintains comprehensive documentation related to API discharge management:

Record	Responsibility	Retention
API Wastewater Characterisation Reports	EHS / QC	5 years
API Risk Assessment Records	EHS	5 years
Treatment System Performance Records	EHS / Engineering	5 years
API Discharge Monitoring Records	EHS / QC	5 years



Regulatory Compliance Reports	EHS	5 years
Customer Reporting Records	EHS / Business Development	5 years
Spill and Incident Reports	EHS	5 years
Training Records	HR	3 years
Equipment Maintenance Records	Maintenance	5 years
Analytical Method Validation Records	QC	5 years

All records are retained for a minimum of five years, or longer where required by regulations, customer requirements, or Alchem International's internal data-retention policy.

9. REVIEW AND CONTINUOUS IMPROVEMENT

9.1 Policy Review

This Policy will be reviewed annually by the Production Head to ensure its continued relevance and effectiveness. The next review date is **01.10.2027**. Once the policy is reviewed, it will be approved by the Director of the company.

9.2 Continuous Improvement

Alchem International fosters a strong culture of continuous improvement in API discharge management through:

Initiative	Description	Frequency
Performance Reviews	Monthly and annual reviews of API discharge performance, treatment efficiency, and compliance status.	Monthly / Annually
Technology Evaluation	Ongoing evaluation of emerging treatment technologies for API removal.	Continuous
Pilot Studies	Conducting pilot studies on new treatment technologies before full-scale implementation.	As needed
Research Collaboration	Collaborating with technology providers, research institutions, and industry experts.	Continuous
Employee Engagement	Encouraging employee suggestions and Kaizen initiatives for API discharge reduction.	Continuous
Benchmarking	Benchmarking against pharmaceutical industry best practices and customer expectations.	Annually
Training and Awareness	Regular training on API discharge prevention, treatment technologies, and environmental protection.	Annually



Target Review	Annual review of progress toward FY 2030-31 targets and adjustment of strategies as needed.	Annually
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9.3 Review Triggers

This policy will be reviewed earlier than the scheduled annual review if:

- Significant regulatory changes occur
- Major incidents of API discharge occur
- Customer requirements change
- New treatment technologies become available
- Organisational restructuring occurs
- Audit findings indicate a need for review
- Progress toward FY 2030-31 targets deviates significantly

10. COMPLIANCE

All API discharge management systems at Alchem International are designed, implemented, and reviewed to meet or exceed:

Requirement	Source
Environment Protection Act, 1986	India
Water Act, 1974	India
CPCB/SPCB Norms for Pharmaceutical Industry Effluent	India
Hazardous and Other Wastes Rules, 2016	India
Stockholm Convention on POPs	International
AMR Industry Alliance Framework	Industry
Pharmaceutical Supply Chain Initiative (PSCI)	Industry
Customer-specific API discharge requirements	Customer
ISO 14001	International
WHO Guidelines on Pharmaceutical Wastewater	International

Dedicated EHS personnel:

- Monitor regulatory updates and evolving compliance obligations



- Update SOPs, training modules, and operational controls accordingly
- Engage with accredited laboratories, authorised vendors, consultants, and authorities to maintain high standards of safety, compliance, and sustainability

11. APPROVAL

This API Discharge Management Policy has been approved by the Senior Vice President of Alchem International Private Limited.

Approved By:

[Sunil Malik]



Alchem International Private Limited

Date: 01.06.2026

DOCUMENT CONTROL

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