MOREPEN LABORATORIES LIMITED
CIN: L24231HP1984PLC006028
Registered Office: Village Morepen, Nalagarh Road, Near Baddi Distt. Solan, Himachal Pradesh – 173 205
Email: plants@morepen.com, Website: www.morepen.com
Tel.: +91-1795-266401-03, 244590, Fax: +91-1795-244591

Corporate Office: 2nd Floor, Tower C, DLF Cyber Park, Udyog Vihar-III, Sector-20, Gurugram, Haryana-1221016
Email: corporate@morepen.com, Website: www.morepen.com
Tel.: +91-124-4892000

Document No.: RPU-POL-001 | Issue Date: 1st Jan 2025 | Revision No.: 00

Responsible Product Use Policy

1. Purpose

Morepen Laboratories Ltd. is committed to protecting the health and safety of customers and consumers through the development, manufacture, and supply of high-quality pharmaceutical products, as well as protection of the environment through responsible management, storage, handling and disposal. This policy articulates our dedication to minimization of environmental; health and safety risks associated with our products and ensuring customers and consumers have the necessary information and support for safe and responsible use of our products.

2. Scope

This policy applies to all products developed and marketed by Morepen Laboratories Ltd., including finished pharmaceutical products, active pharmaceutical ingredients and healthcare products. It covers all business units involved in research & development, manufacturing, quality assurance, regulatory compliance, distribution and customer support.

3. Policy Commitment

Morepen Laboratories Ltd. commits to:

- Uphold strict adherence to Good Manufacturing Practices (GMP), global regulatory requirements such as Central Drugs Standard Control Organization (CDSCO), World Health Organization (WHO) and International Council of Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH guidelines), and internal quality standards to deliver safe products in addition to following all applicable legal requirements.
- Proactively identify and mitigate any potential environmental, health and safety adverse matters that are associated with material sourcing, formulation, manufacturing, packaging, storage, and distribution and disposal, with an emphasis on end of product life cycle use.

Prepared By	Reviewed By	Approved By
Manager QA	GM – QA/QC	Director

- Foster a culture of continuous improvement and accountability in environmental, health and safety management.

4. Objectives

- **Product Safety and Quality Assurance**
  All products shall meet stringent quality criteria ensuring safety, efficacy, and consistency. Regular audits and inspections by regulatory authorities and customers to ensure continuous compliance.
- **Risk Assessment and Prevention**
  Systematic risk assessments are conducted at all stages from R&D to post-market to identify adverse matters and implement controls to prevent or minimize risks to customers as well as environment.
- **Clear Customer Communication**
  Provide accessible, comprehensive product information including labelling and packaging and material safety data sheets that detail indications, contraindications, dosage, side effects, handling, storage and disposal instructions.
- **Effective Pharmacovigilance and Incident Reporting**
  Establish a robust system for collecting, monitoring and analyzing adverse event reports. Ensure timely investigation, root cause analysis and corrective actions to protect customer safety.
- **Training and Capacity Building**
  Conduct regular training programs for employees on customer health and safety requirements, regulatory changes, and ethical standards to reinforce shared responsibility inclusive of measures to be taken for the protection of environment.
- **Regulatory Compliance and Transparency**
  Adhere to all applicable compliance requirements and guidelines in every jurisdiction where products are marketed and sold. Maintain transparent communication with key stakeholders with special mention to investors, regulatory authorities and customers.
- **Sustainability and Ethical Responsibility**
  Promote ethical practices that prioritize the welfare of customers and stakeholders while aligning with broader sustainability goals.

Prepared By	Reviewed By	Approved By
Manager QA	GM – QA/QC	Director

5. Roles and Responsibilities

Top Management	Provide leadership, resources, and oversight to ensure policy implementation and continual improvement.
Quality Assurance Team	Develop quality management systems; conduct audits; ensure compliance with GMP and regulatory standards.
R&D Department	Incorporate safety considerations into product design and development; conduct risk assessments.
Production Department	Follow GMP protocols and safety standards throughout production and packaging.
Pharmacovigilance Team	Monitor and evaluate adverse events; coordinate with regulatory bodies for reporting and risk mitigation.
Customer Support	Address customer inquiries related to product safety, facilitate adverse event reporting.
Environmental, Health and Safety (EHS)	Identify adverse and mitigating measures related to EHS matters.
Sustainability	Adopt appropriate, economic, environmental, social and governance measures for the overall sustenance of the organization.

6. Monitoring and Measurement

- Establish key performance parameters, such as, number of product recalls, adverse event resolution time and training completion rates.
- Perform regular audits and self-assessments of internal departments & suppliers to evaluate compliance effectiveness.
- Maintain a documented system for recording incidents and corrective measures.

Prepared By	Reviewed By	Approved By
Manager QA	GM – QA/QC	Director

7. Continual Improvement

- Review policy and practices on periodic basis or as per requirement.
- Regular feedback through loops from consumers and healthcare professionals to enhance product responsibility protocols, wherever required.

8. Communication and implementation

- Make the policy publicly available via company website and internal platforms.
- Provide appropriate training to concerned stakeholders for effective implementation of the policy.

9. Review

- This policy shall be reviewed on a periodic basis or as and when required and accordingly revised if felt necessary.

Prepared By	Reviewed By	Approved By
Manager QA	GM – QA/QC	Director