POLICY ON DISTRIBUTION

INTRODUCTION:

……. understands that distribution is an integral part of supply chain management.

The document provides the policy details on Good Distribution Practices to ensure that the quality of medicinal and pharmaceutical products are maintained throughout the supply chain moving forward in the distribution chain from site of manufacture to end user customer and to products moving backwards from end user to …….

SCOPE:

This policy is applicable to all products (Finished, API and Medical devices) which are stored, transported and distributed by …….

POLICY DETAILS:

This policy involves the activities in distribution chain at all the stages of legal supply chain resulting in maintaining quality and integrity of medicinal products.

The goods shall be stored in a licensed premises only.

Distribution involves series of activities taking place throughout the process.

Receipt:

- All incoming goods shall have complete documentation including the purchase order and excise invoices as per requirement.
- Storage, Distribution and Transportation:
- The product shall be stored as per labelled condition.
- Environmental storage condition shall be monitored and documented. No material shall be stored directly on floor
- Storage of material shall be so as to prevent mixup.
- Returned material shall be stored in a secure and quarantined location till disposition decision is made.
- Periodic stock reconciliation shall be performed by way of actual and recorded stock. FEFO (First Expiry First out) system shall be followed.
- There shall be written procedure for handling destruction
- Approved procedure for management of warehouse activities shall be place.
- Transportation shall be performed using vehicles from approved vendors and recommended storage conditions shall be maintained during transportation.
- Records of distribution shall be maintained to permit full batch traceability.

Dispatch:

All outgoing consignments shall be checked and verified before dispatch.
Transportation shall be as per environmental condition detailed on the label.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not Applicable

ABBREVIATIONS:

API	:	Active Pharmaceutical Ingredient
EU	:	European Union
GDP	:	Good Distribution Practice
ICH	:	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
WHO	:	World Health Organization

REFERENCES:

CFR: Code of Federal Regulations Title 21

ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

EU GDP Guideline on Good Distribution Practice of Medicinal Products for Human Use WHO Good Distribution Practices for Pharmaceutical Products: 2005