1 Purpose

The purpose of this Guideline is to provide guidance on the warehousing and distribution of commercial products.

2 Scope and Applicability

This Guideline is applicable to:

All products, including intermediates, active pharmaceutical ingredients, bulk formulated and finished products

All commercial manufacturing sites and marketing companies, its licensees, joint-ventures and contractors

3 Definitions

3.1 Active Pharmaceutical Ingredient

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product that when used in the production of a drug becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

3.2 Intermediate

Material produced during manufacture that undergoes further change or purification. Intermediates may or may not be isolated.

3.3 Bulk Formulated Product

A pharmaceutical product (Formulated Drug/Formulated Product) held in large intermediate or shipping containers and ready to be filled into primary containers.

3.4 Finished Product

A product which is packaged and labeled for supply to a wholesaler, hospital, pharmacy, doctor or patient.

3.5 Storage Life Management System

The global electronic documentation management system used by Operations and Pharmaceutical Analytical R&D, containing information on shelf lives and storage conditions for both commercial products and products used in clinical trials.

4 Responsibilities

Records, including records of orders & distribution

Handling of returned and recalled products.

Management of personnel (including training)

Management of product shipped ahead of clearance

These procedures should be approved, signed and dated by the person responsible for the quality system.

5.2.2 Records should be kept of each despatch/receipt transaction, showing the following information:

Date/time of dispatch/receipt
Name of the product including strength
Package size
Quantity
Batch number
Name and address of customer/supplier
Article number or similar

5.2.3 Records should be made at the time each operation is undertaken and in such a way that all significant activities or events are traceable. Records should be clear and readily available. They should be retained for shelf life plus one year or at least five years, whichever is the longer. Local legislative and regulatory requirements with respect to time the documents should be retained, take precedence over this Guideline, so long as the minimum requirements stated above are met.

5.3 Warehousing Premises and Equipment

5.3.1 Premises and equipment should be suitable and adequate to ensure proper storage and distribution of products. Any special storage requirements shall be met.

5.3.2 The storage facilities should be clean and free of litter, dust and pests. A pest control program should be implemented.

5.3.3 Adequate precautions should be taken against spillage or breakage, attack and contamination by micro-organisms or other products. Materials and equipment necessary to contain and clean-up spills should be readily available.

5.3.4 Receiving and dispatch bays should protect products from the weather. The reception area should be separate from the storage area. Reception areas should be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage. Deliveries should be examined at receipt in order to check that containers are not damaged and that the consignment corresponds to the order.

5.3.5 Products should be stored in an orderly manner to allow batch segregation. There

5.4 Transportation and Distribution

5.4.1 Products should only be distributed to authorized wholesalers or to other units authorized to receive/supply product. This may include sales representatives responsible for finished product distribution.

5.4.2 company units, its licensees, joint-ventures and contractors should engage haulage contractors to distribute the products in such a way that:
Product identification is maintained.
Products do not contaminate, and are not contaminated by, other products or materials.

Adequate precautions are taken against spillage, breakage, theft or tampering.
Products are secure and not exposed to unacceptable degrees of heat, cold, light, moisture or other adverse influence, nor to attack by micro-organisms or pests.

5.4.3 Products requiring controlled temperature storage should also be transported by appropriately specialized means and a temperature monitoring device should accompany each delivery.

5.4.5 APIs, intermediates, bulk tablets/capsules being transported between own sites/functions or being received from contractors/vendors will be sealed properly.

5.5 Distribution under Quarantine

Manufacturing units may need to distribute products under quarantine status to another own unit using the time in transit for Quality Assurance/Quality Control testing. This should be carried out in accordance with proper procedure.

5.6 Customer Returns

5.6.1 Customer returns should be handled according to appropriate procedure.

5.6.2 Non-defective finished product, which has been returned, should be separated from saleable stock to prevent redistribution until a decision has been reached regarding their disposal, or recovery.

5.6.3 Finished product, which has left the care of the wholesaler, should only be returned to saleable stock if it meets the proper requirements.

5.6.4 Records of returns should be kept. The responsible person should formally release goods suitable for return to saleable stock. Products returned to saleable stock should be located such that distribution of stock based on expiry date is upheld.

5.7 Recalls

5.7.1 An emergency plan for recalls should be described in writing.

5.7.2 Recall operations should be recorded at the time they are carried out. If requested

