

## **WAREHOUSE**

- Maintaining proper storage condition for pharmaceutical products and paramedical is vital to ensure their quality, safety and efficacy.
- Factory stores will invariably be receiving duly approved raw materials and packaging materials from third party.
- A suitable space is provided to raw material, handling of raw & packaging materials required for manufacturing, including packaging of pharmaceuticals.

## **PURPOSE**

- To enable the fastest and cheapest transport of drugs and medical equipment from suppliers to beneficiaries.

There are mainly 3 stages:

- Purchase of pharmaceutical products.
- Storage of ordered products.
- Distribution of stocked products

## **GOOD WAREHOUSING PRACTICE**

- Stock received factory should be received with proper documents detailing the names of product, the batch number, the number of units of final packs of each batch, the date of dispatch and the quality control status of the batches.
- The stock control system must be such that only passed batches of products are issued for distribution.
- Stocks should be stored product wise to enable quick identification and control of stock movement.
- Stocks should therefore be racked and stored in a manner that earlier stocks are earlier accessible than the later ones.
- The picking and assembling areas should be so arranged as to minimize the distance travelled by warehouse operators.
- Picking stocks should be located on shelves at convenient heights and with proper labels which clearly identify the products.
- Picking and assembling of products according to orders should be done against standards, data and serially numbered documents.
- Assembled products should be checked for accuracy of quantities and identities of products ordered.

- Batch details should be recorded in relevant documents. Finished products outer packs should be so prepared and packed for transport that only released products are dispatched.
- Adequate precautions are taken to prevent spillage, breakage or pilferage in transit.
- The unit product packs should be not contaminated by other products.
- Vehicles which carry the final packaged stocks of products should be so selected that-
  - They are clear, dry and sufficiently protected from rain and other weather factors
  - They are free from infestation
  - They do not give off strong odors which may contaminate the products
  - They are suitable to withstand the weight of the load they carry

## **RULES FOR WAREHOUSING**

- Systematic storage of the delivered goods
- Use of pallets for better air circulation & protection against rodents
- Keeping a space at least 50cm between the rows of pellets walls
- Providing each product have only one specific place
- On shelves clear labelling of products should be there
- Adequate space should be provided for each good
- Provide separate stock card for each product
- All boxes in stock should be closed
- Flammable products should store in separate place

## **CHARACTERS OF GOOD WARE HOUSE**

- Properly cleaned
- Good preservation of drugs & equipment
- Provide safety for staff & stocked goods
- Control of air, light & temperature
- Products to be purchased according to needs
- Order the destruction of unsuitable products.
- Promote rational use of pharmaceutical products

## **WARE HOUSE STAFFS**

Under the supervision of responsible pharmacist

## **DUTIES**

- Reception of supplies

- storage of stocks of goods
- recording of movement of products
- monitoring of refrigerators
- checking warehouse temperature twice daily
- maintenance of equipment

## **MATERIALS MANAGEMENT**

### **RAW & PACKAGING MATERIALS STORAGE**

- Storage condition: Special storage area with controlled temperature, humidity & stored off from the floor.
- Segregation:
  - to be sampled
  - under test
  - approved
  - rejected
  - hazardous
  - non-hazardous materials

### **STORAGE OF PACKAGING MATERIAL**

- Bottles, vials, ampoules, tins, tubes should be stored in a manner that they do not contaminate by extraneous matter
- Printed packaging material also stored properly
- Printed materials such as labels, printed films/ foils/ laminates, cartons should keep in storage cupboards
- Preventing mix up of printed & non printed materials
- Physical segregation of printed & labelled containers should be made
- Special precautions are needed for the storage of — packaging labelling-controlled products
- Appropriate storage condition to be provided (air conditioning, aluminium foil)

### **HANDLING & ISSUE – RAW MATERIALS**

Attention to be made for

- prevent cross contamination - health of personnel handling materials
- containers should be closed properly
- materials that support microbial growth are handled carefully
- materials issued only against authorized raw material requisition order

- Materials safety data sheets shall be prepared for all such materials that are known to pose health and safety hazards.
- Personnel protective devices like gloves, facemasks etc. should be used to avoid health hazards.
- Adequate dust extraction system should be provided to suck away fine dust as to prevent cross-contamination.
- Material prone to support microbial growth shall be handled to minimize/avoid microbial contamination from the environment.

### **HANDLING&ISSUE: PACKAGING MATERIALS**

- Packaging materials issued to production only against — packaging materials order
- Care should made to check for only right packaging materials to be issued
- Unlike raw materials, exact quantity of packaging materials to be issued
- Unused packaging materials returned to the warehouse & will accompanied by authorized documents

### **WARE HOUSING OF FINISHED PRODUCTS**

- For avoiding deterioration, spillage or breakage
- Safe, orderly & dispatch of all products
- Cold storage areas have temperature monitoring & recording devices
- Racking & shelving system should have good mechanical strength
- Stock received from factory with proper documentation (name, batch number, date of dispatch)
- Finished products which are — "under test" must be quarantined & segregated from passed stocks
- Stock should be stored product wise to enable quick identification & controlled stock movement
- Store rotation should be on — first in, first out basis

### **WARE HOUSING OF RETURNED GOODS**

- Stocks should be carried out only consultation with quality-controlled manager
- Returned goods must be isolated on receipt, clearly identified & records regarding reason for the return
- QC manager should examine whether these goods are reprocessed or destroyed
- Reprocessing of returned should be done according the instruction of QC manager

## **SANITATION: -**

- Written sanitation programmes should be available.
- These should include validated cleaning procedures for premises and equipment, a quality standard for water, instructions for hygiene when manufacturing and handling goods, and instructions relating to the health, hygienic practices, and clothing of personnel and the disposal procedures for waste materials and unusable residues.
- Eating, smoking, and unhygienic practices should not be permitted in manufacturing areas.
- There shall be written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents and cleaning and sanitizing agents. cleaning procedure to be followed, including equipment and materials.

## **MAINTANANCE: -**

- Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair.
- Deterioration of buildings not only presents a poor image of the facility; it can also impact on product quality.
- Cracks and holes in walls, floors, or ceilings can provide access for insects, rodents, birds, dirt, or microorganisms.
- They can also hinder cleaning and sanitation, thereby increasing the potential for cross contamination or microbial multiplication.
- Floor cracks can also become a safety hazard for people or even dislodge materials from trucks.
- The ingress of water from roof leaks can cause significant damage to materials and equipment, give rise to electrical failures and fires and result in damage to the basic structure of the building.
- Additionally, holes in the roof or near the tops of buildings provide ready access to birds, which may then be encouraged to nest within the building.

## **STOCK MANAGEMENT: -**

- To ensure continuity of supplies.
- To avoid over stocking.
- Stock management will set out to; monitor stock levels monitor consumption anticipate delivery time for order activation.
- Issuing of material: - store should issue raw and packaging materials on the basis of FIFO (first come first out) basis.

- Entry and exit of every consignment of materials should be entered on the stock card.
- Issuing of materials should do on the basis of raw and packaging materials required in manufacturing process. while issuing hazardous and explosive materials, the operation should be supervised to prevent any mistake

## **SOPs OF WAREHOUSE**

SOPs are reference tools for the ware houses. It should be clear accessible to the ware house staff.

Instructions apply to the organization & management includes

- direct purchase from mission
- Purchase via head quarters
- Reception of local orders
- Reception of imported products
- Un packaging of products
- labeling of products
- Storage of products
- Computerized stock management
- Management of narcotic drugs
- Management of outdated products
- Withdrawal of batches
- Inventories
- Human resources management

## **AUDITS**

- To assessing the activities & organization of ware housing
- To access whether initially set activities & quality objectives been reached
- Whether procedures correctly written, respected, reviewed
- Does the warehouse guarantee safety standards

## **DOCUMENTATION**

Following records should be in place:

- Receiving material (delivery challan, invoice, check list)
- Issuing material (BMR/BPR issuance copy)
- Finished Good (receiving packing list, outgoing invoice, delivery challan, ARE1(Application for Removal of Excisable Goods for Export) copy with authorized signature)

- Training
- Monitoring temperature and humidity
- Cleaning operation, Pest control
- Calibration
- Preventative maintenance
- Recall, Complaints
- Inventory (Inward, stock registers)
- Log of signature (formats)