SHREE H. N. SHUKLA INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH

B.PHARM

(SEMESTER –VII)

SUBJECT NAME: QUALITY ASSURANCE

SUBJECT CODE: BP706TT

UNIT 05 (b): WAREHOUSING

Content

Warehousing: Good warehousing practice, materials management

Good warehousing practice

"Warehousing and storage is an act of storing and assorting the finished goods so as to create maximum time utility at minimum cost"

Need for storage arises both for raw material as well as finished products.

STORAGE involves proper management for preserving goods from the time of their production or purchase till actual use. When this storage is done on a large scale and in a specified manner it is called WAREHOUSING.

Now a days, many private firms are turning to distribution centers rather than constructing the warehouses. Warehouse is the key part of the supply chain.

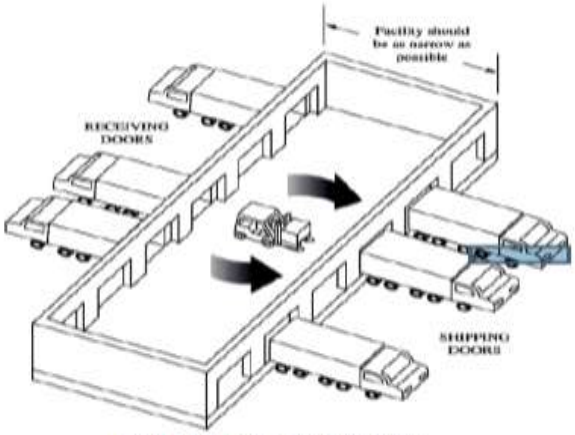
According to Robert Hughes-
"Warehousing is the set of activities that are involved in receiving and storing of goods and preparing them for reshipment "

Warehousing of drug products shall be include and followed.

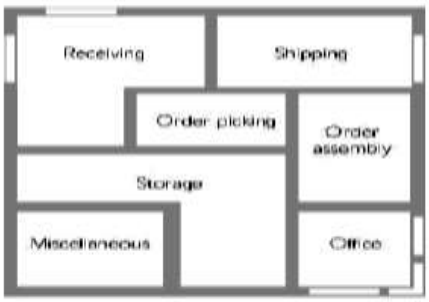
a) Quarantine of drug products before release by the quality control unit,
b) storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected.

DESIGN AND LAYOUT

DESIGN CONSIDERATION



Ideal Facility for Pure Supplier Consolidation
(Full Pallet Movement)



Warehouse Space Requirements

Following should be maintained in warehouse.

1. Premises
2. Security
3. Temperature and humidity control
4. Equipment
5. Personnel
6. Sanitation
7. Receipt of incoming goods
8. Assembling orders and issuing goods
9. Packing for transportation
10. Transport

- **Premises:** Premises should be of suitable size and construction to facilitate cleaning, maintenance and orderly, segregated storage.
  Storage areas must be designed to provide adequate:
  - Lightening
  - Ventilation
  - Temperature
  - Sanitation
  - Humidity
  - Space
  - Equipment
  - Security conditions

  Each material should be stored separate from other materials to avoid the risk of cross contamination. Incoming materials should be quarantine until approved by the responsible person.

  A segregated area must be provided for returned, recalled and rejected goods prior to a decision on further action.

  A secure, segregated area must be provided for the storage of controlled drugs. A separate, designed area should be provided for the assembly of customer orders.

- **Security:** Storage areas should be provided with security to prevent theft or unauthorized entry.

- **Temperature and Humidity Control:**
  Temperature control: All drug products must be stored at appropriate conditions as stated on the label of the product. The temperature of all storage areas should be regularly monitored.

  Controlled temperature storage areas should be equipped with recorders and devices which indicate when the specific temperature range has not been maintained. A written procedure must specify the action to be taken when this occurs.

Control should be adequate to ensure that all parts of the storage area are kept within the specified temperature range.

There should always be a backup system in case main system fails.

Humidity Control: The humidity of all storage areas should be regularly monitored using recorders and devices which document the humidity measures.

If the product spec require a specific humidity, a written procedure must specify the action to be taken when the specified humidity range has not been maintained.

Establish a normal operating baseline of humidity if no specific value is required. Records of temperature and humidity in all storage areas should be reviewed and retained by a designated responsible person.

- **Equipment:** There should be a planned preventative maintenance programme in place , recording and control equipment should be calibrated and checked at defined intervals by appropriate methods.

  Alarm set-points should be checked on periodic intervals.

  A computerized system used for stock control/distribution should be validated

- **Personnel:**
  - The organization chart should be in place.
  - There should be a sufficient number of staff.
  - There should be clearly defined job description.
  - Personnel should be trained in relation to good storage and distribution practice and to the duties assigned to them.
  - The current records of training should be in place.
  - The trainers should have established and approved qualification.

- **Sanitation:**
  A written sanitation program should be in place indicating the frequency and method of cleaning the facility.

  Storage areas should be cleaned and accumulated waste removed at regular intervals.

  A pest control program should be in place.

  Smoking, eating and drinking should be permitted only in segregated areas, and not in those areas used for the storage and handling of final drug product.

  Spills involving drug products must be promptly cleaned-up and rendered safe in accordance with the relevant health and safety requirements for the product.

  Adequate toilet and changing facilities should be provided, and they should be segregated from the main storage and order assembly areas.

- **Receipt of incoming goods:**
  - It should be carried out according to approved adequate SOP:
  - Visually examine for identity against the relevant supplier's documentation
  - Visually examine for damage
  - sub-divide according to batch numbers if more than one batch
  - reject product if damage or otherwise unfit for use
  - handle high security materials (control drug, high value items, products requiring a specific storage temperature)
  - confirm with signature that receiving goods are as specified by supplier or if not provide adequate comments

- **Assembling orders and issuing goods:**
  - It should be carried out according to approved adequate SOP:
  - Pick up goods according to formal dispatch documents
  - Assemble complete order
  - Visually examine for identity and completeness
  - Visually examine for damage
  - Confirm with signature properly assembled order
  - Prepare adequate shipping package to protect any damage of goods, seal pack and provide relevant identification
  - The heat sensitive drugs if not transported by appropriate specialized means should be provided isolated packing

- **Packing for transportation:**
  Products should be packed in such a way that:
  - the identification of the product is not lost,
  - the product does not contaminate and is not contaminated by other products or materials
  - adequate precautions are taken against spillage and breakage of packing.

  There should be in place documented evidence that the insulated packs ensured adequate transport conditions with regards to:
  - product quantity
  - ambient temperature
  - maximum delivery time.

- **Transport:** Products should be transported in such a way that:
  - The safety, identity, strength, quality and purity of the product is not lost
  - The product is not contaminated by other products or materials
  - Adequate precautions are taken against spillage or breakage
  - The product and its package are not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influences nor to attack by micro-organisms or pests

– Drug products requiring controlled temperature storage by appropriate specialized means or should be packed with adequate insulation

Documents should be provided to cover all shipments. These document should include as minimum:

- name of the product
- quantity of the product
- special storage and handling instructions

Material Management

It is an organizational concept, which has the authority & responsibility of all activities, principally concerned with the flow of materials in the organization.

Operations involved in the flow of materials are – Purchasing, Inventory control, Receiving, Storing, Production scheduling & Shipping of finished products.

Most industries buy materials, transport them in to the plant, change the materials in to parts, assemble parts in to finished products, sell and transport the product to the customer. All these activities of purchase of materials, flow of materials, manufacture them in to the product, supply and sell the product at the market requires various types of materials to manage and control their storage, flow and supply at various places.

Hence, material management works in liaison with production, marketing, sales & quality control.

OBJECTIVES:

- Profit maximization
- Lowering inventory investment & increasing the inventory turnover by cutting the costs related to purchases.
- Improvement in customer services
- Globalization of its product sales
- Meet the technological changes
- Reduction in manufacturing and other cost
- Selection of alternative materials
- Ensuring cooperation of all departments.
- Providing best services to the level of customer's delight.

Functions of Material management:

The total material management activity starts right from selection of vendors for row material and packaging material to dispatch of finished products to its destination. All incoming materials should be quarantined immediately after received or processing, until they are released for use or distribution.

- Material planning & programming.

- Simplification, standardization & value analysis.
- Inventory control & management.
- Purchasing of materials in desired quantities without delays.
- Receiving of incoming materials.
- Storage, preservation & administration of materials.
- Transportation (internal & external) & material handling.
- Disposing of rejects & obsolete materials.
- Improving operation efficiency through training.

TYPES OF MATERIAL HANDLING SYSTEMS

- Conveyors
- Fork- lift Trucks
- Cranes
- Hoists
- Slides
- Chute
- Lifts
- Tractors and Trailers

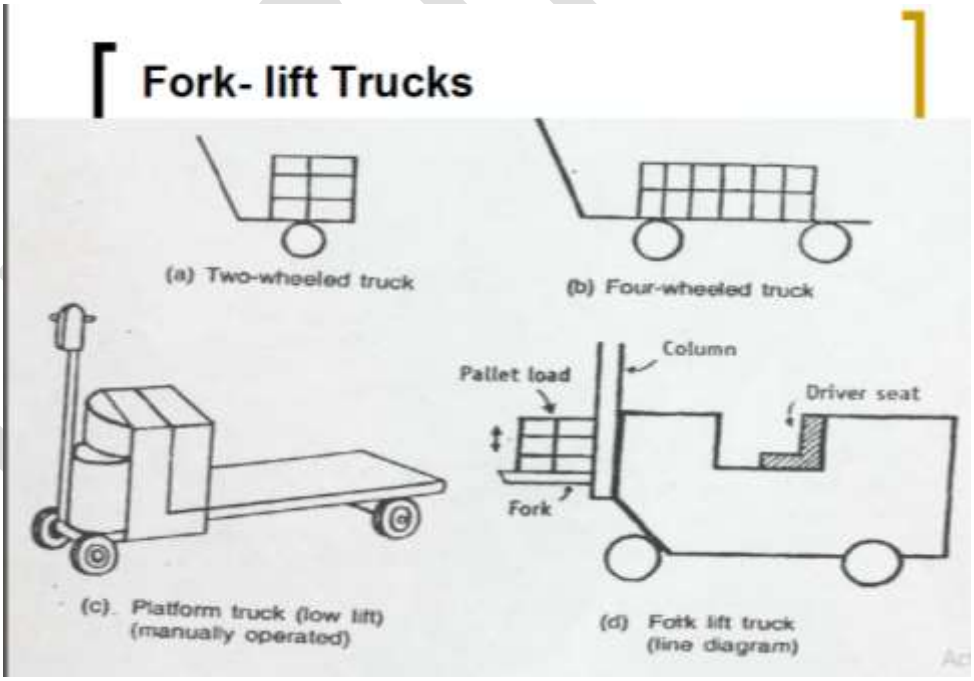
Conveyors:

Belt conveyors are used in transporting containers (bottles) for filling, capping, sealing, labeling, pasting, visual inspection in production of injectables, liquid orals, ointments and jellies.

Other conveyors- Pneumatic conveyor, roller conveyor, slat conveyor, wheel conveyor, apron conveyor, pusher conveyor, bar conveyor and bucket conveyor.

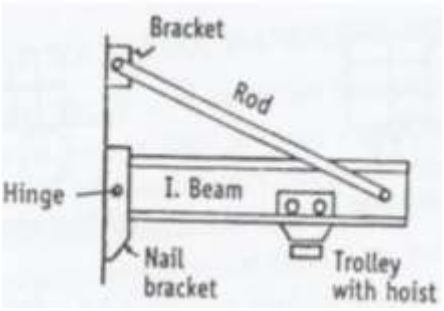
Fork- lift Trucks:

It consist of forks attached to a column of the truck. Fork can be lifted upto the desired height with material (boxes) on them. The material can be stacked at the proper place very close to the roof in warehousing & shinning area. Fork-lift trucks are used for short distance (40 to 70 meters) travel. These are used for indoor applications.



Cranes:

Cranes are employed for lifting & lowering of bulky items, packages & boxes. These find applications in heavy engineering industry & generally in intermittent type of production.

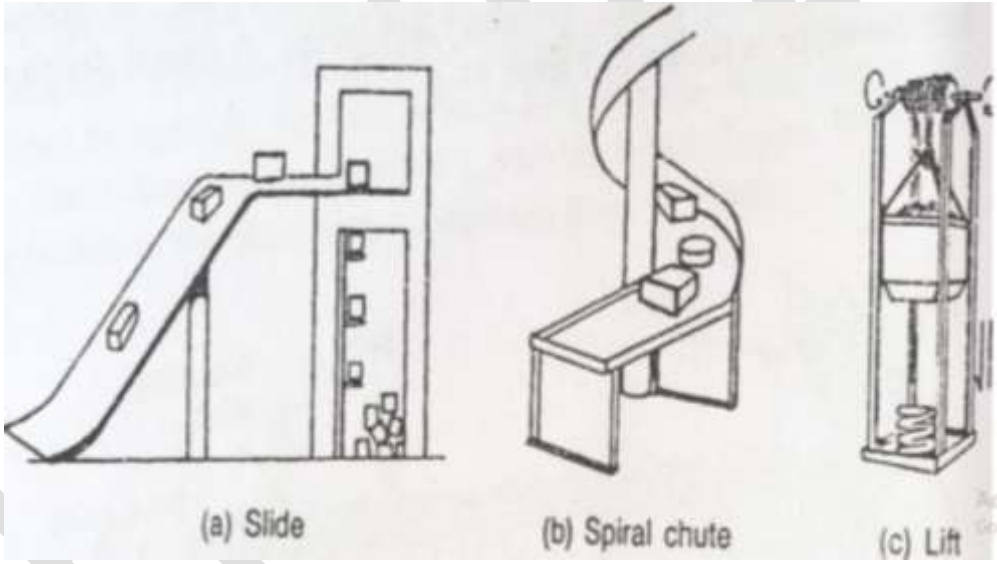


Slides Chute and Lifts:

Slides Chute and Lifts Slides can be straight, spiral & vibrating, & made up of wood or steel. These transfer small jobs that can slide down under gravity. Vibrating slides transport material up & inclined.

Chutes generally deliver the feed material directly onto the conveyor to reach the destination further. Spiral chutes are used for transporting sealed vials from septic area to packing section using gravity principle.

Lifts are used to transport material up in multi-storeyed Plants. It is a fast & flexible equipment for floor to floor Travel.



Tractors and Trailers:

Three wheeled or four wheeled tractors are employed & fitted with an IC engine drive. These are used for outdoor applications.

Trailers are loaded with the material & attached to the tractor. It can be either uncoupled from the tractor or the material can be dumped in respective stations.