



# PACKAGING of

# PHARMACEUTICALS



Pharmaceutics I  
Unit III

# INTRODUCTION

- Packaging is the science, art and technology of enclosing or protecting products for distribution, storage, sale, and use.
- Packaging also refers to the process of design, evaluation, and production of packages.
- Pharmaceutical packaging can be defined as the economical means of providing presentation, protection, identification, information, convenience, compliance, integrity and stability of the product.

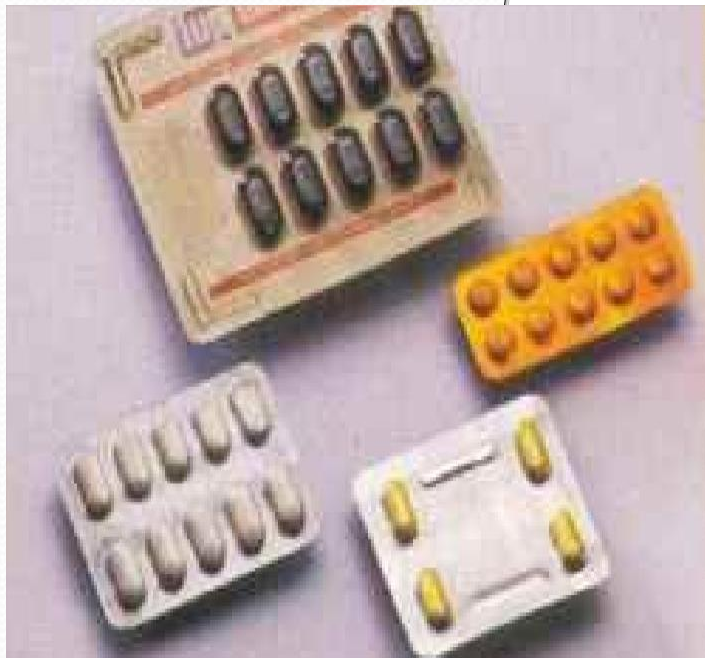
# FUNCTIONS OF PACKAGING

- **Product Identification:-** Packaging greatly helps in identification of products.
- **Product Protection:-** Packaging protects the contents of a product from spoilage, breakage, leakage, etc.
- **Facilitating the use of product:-** Packaging should be convenient to open, handle and use for the consumers.
- **Product Promotion:-** Packaging is also used for promotional and attracting the attention of the people while purchasing.

# TYPES OF PACKAGING

**Primary packaging-** is the material that first envelops the product and hold it. This usually is the smallest unit of distribution or use.

Ex. Aerosol spray can, blister packs, bottle



## Secondary packaging -

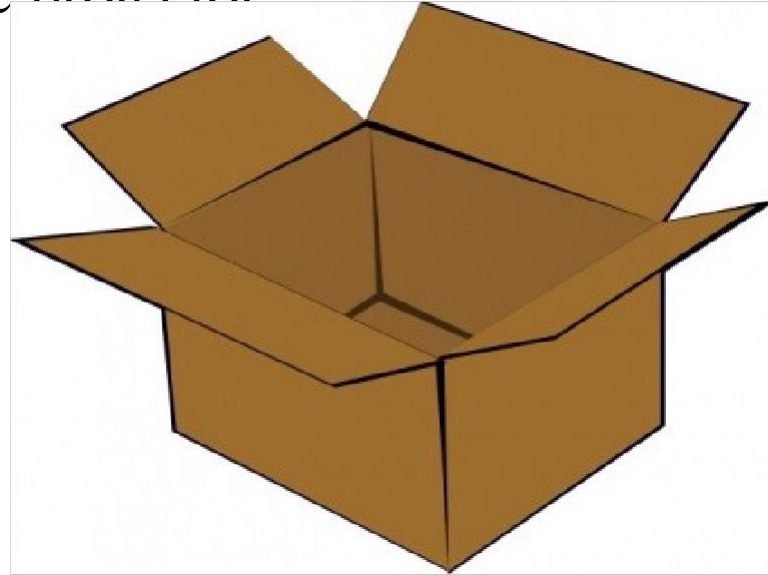
Is outside the primary packaging perhaps used to group primary package together.

Ex. Boxes, cartons



**Tertiary packaging-** is used to bulk handling and shipping.

Ex. Barrel, container, edge protector



## **PACKAGE TESTING**

- Drop test
- Vibration test
- Shock test
- Inclined impact test
- Revolving drum test

# **TYPES OF PACKAGING MATERIALS USED FOR PHARMACEUTICAL PACKAGING**

- Glass
- Plastics
- Rubbers
- Paper/card boards
- Metals



## **THE CHOICE OF PACKAGING MATERIAL WILL DEPEND UPON:**

- The degree of protection required
- Compatibility with the dosage form
- Customer convenience e.g. size, weight of dosage form,
- Filling method
- Sterilization method to be employed and cost

## **GLASS:**

Glass has been widely used as a drug packaging material

### Advantages

- They are transparent.
- They have good protection power.
- They can be easily labelled.
- Economical
- Variety of sizes

### Disadvantages

- Glass is fragile so easily broken.
- Release alkali to aqueous preparation

## COMPOSITION OF GLASS

- Sand (silicon dioxide) Soda ash (sodium carbonate)  
Limestone (calcium carbonate) Cullet (broken glass) -  
aluminium, boron, potassium, magnesium, zinc, barium,
- Amber: light yellowish to deep reddish brown, carbon  
and sulphur or iron and manganese dioxide
- Yellow: Compounds of cadmium and sulphur
- Blue: Various shades of blue, cobalt oxide or  
occasionally copper (cupric) oxide
- Green: iron oxide, manganese dioxide and chromium  
dioxide

## MANUFACTURE OF GLASS:

The four basic processes used in the production of glass are:

- **Blowing** uses compressed air form the molten glass in the cavity of metal mold.
- In **drawing** , molten glass is pulled through dies or rollers in cavity to shape the soft glass.
- In **pressing** mechanical force is used to press the molten glass against the side of a mold.
- **Casting** uses gravity or centrifugal force to cause molten glass to form in the cavity of mold.

## **TYPES OF GLASS**

- Type I—Highly resistant borosilicate glass
- Type II—Treated soda lime glass
- Type III—soda lime glass
- NP—soda glass (non parenteral usage)

## **Type I-borosilicate glass**

- Alkalinity is removed by using boric oxide to neutralized the oxide of potassium and sodium
- It is highly resistant glass.
- It has high melting point so can with stand high temperatures.
- It is more chemically inert than the soda lime glass
- It can resist strong acids,alkalies and all types of solvents.
- Reduced leaching action.

### **USES:**

- Laboratory glass apparatus.
- For injection and water for injection.

## **Type II-treated soda lime glass**

Type II containers are made of commercial soda lime glass that has been dealkalized or treated to remove surface alkali

. The de-alkalizing process is known as sulphur treatment.

Sulfur treatment neutralizes the alkaline oxides on the surface, rendering the glass more chemically resistant.

Uses: Used for alkali sensitive products. Infusion fluids, blood and plasma. Large volume container.

## ■ PLASTIC

- Plastics may be defined as any group of substances, of natural or synthetic origins, consisting chiefly of polymers of high molecular weight that can be moulded into a shape or form by heat and pressure.
- Advantages
  - Less weight than glass, flexible
  - Variety of sizes and shapes
  - Essentially chemically inert, strong, rigid Safety use, high quality, various designs
  - Extremely resistant to breakage
- Disadvantages
  - Absorption permeable to moisture
  - Poor printing, thermostatic change



## TYPES OF PLASTICS

### Thermosetting type –

When heated they may become flexible but they do not become liquid

e.g. Urea formaldehyde (UF), Phenol formaldehyde, Melamine formaldehyde (MF), Epoxy resins (epoxides), Polyurethanes (PURs)

### Thermoplastics type-

On heating they are softened to viscous fluid which harden again on cooling.

e.g. Polyethylene {HDPE – LDPE}, Polyvinylchloride(PVC), Polystyrene Polypropylene, Nylon(PA), Polyethylene terephthalate(PET), Polyvinylidene chloride(PVdC), Polycarbonate Acrylonitrile butadiene styrene(ABS)

## **METALS :**

Metals are used for construction of containers. The metals commonly used for this purpose are aluminium ,tin plated steel, stainless steel, tin and lead

### Advantages:

- They are impermeable to light, moisture and gases.
- They are made into rigid unbreakable containers by impact extrusion.
- They are light in weight compared to glass containers.
- Labels can printed directly on to their surface.

### Disadvantages:

- They are expensive.
- They react with certain chemicals

## **COLLAPSIBLE TUBES METAL**

- The collapsible metal tube is an attractive container that permits controlled amounts to be dispensed easily, with good reclosure, and adequate protection of the product.
- It is light in weight and unbreakable
- Most commonly used are tin, aluminium and lead

## **Tin:**

- Tin containers are preferred for food, pharmaceuticals and any product for which purity is considered.
- Tin is the most chemically inert of all collapsible metal tubes .

## **Aluminium:**

- Aluminium tubes offer significant savings in product shipping costs because of their light weight .
- They are attractive in nature

## **Lead:**

- Lead has the lowest cost of all tube metals and is widely used for non food products such as adhesives, inks. paints and lubricants.
- Lead should never be used alone for anything taken internally because of the risk lead poison .
- With internal linings, lead tubes are used for products such as chloride tooth paste.

## **RUBBER:**

- Rubber is used mainly for the construction of closure meant for vials, transfusion fluid bottles, dropping bottles and as washers in many other types of product.

## **BUTYL RUBBER:**

### Advantages:

- Permeability to water vapour .
- Water absorption is very low.
- They are relatively cheaper compared to other synthetic rubbers. Disadvantages:
- Slow decomposition takes place above 130 ° C.
- Oil and solvent resistance is not very good.

## **NITRILE RUBBER:**

- Advantages : Oil resistant due to polar nitrile group. Heat resistant. Disadvantages:
- Absorption of bactericide and leaching of extractives are considerable.

## **CHLOROPRENE RUBBERS :**

- Advantages: Oil resistant. heat stability is good.

## **SILICON RUBBERS:**

- Advantages:

Heat resistance.

Extremely low absorption and permeability of water.

Excellent aging

### Disadvantages:

They are very expensive.

## **TAMPER RESISTANT PACKAGING:**

- The requirement for tamper resistant packaging is now one of the major considerations in the development of packaging for pharmaceutical products.
- Tamper resistant package is one having an indicator to entry in which, if missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred.
- F D A approves the following configurations as tamper resistant packaging: Film wrappers, Blister package, Strip package, Bubble pack, Shrink seals, and bands Oil, paper, plastic pouches, Bottle seals, Tape seals, Breakable caps, Aerosol containers

## **Film wrapper**

- Film wrapping has been used extensively over the years for products requiring package integrity or environmental protection.
- It is categorized into following types:
  - End folded wrapper
  - Fin seal wrapper
  - Shrink wrapper

## **End folded wrapper**

The end folded wrapper is formed by passing the product into a sheet of over wrapping film, which forms the film around the product and folds the edges in a gift wrap fashion.

The folded areas are sealed by pressing against a heated slab. The materials commonly used for this purpose are cellophane and polypropylene.



## **Fin seal wrapper**

- The seals are formed by crimping the film together and sealing together the two inside surfaces of the film, producing a fin seal.
- Fin sealing is superior than end folded wrapper With good seal integrity the over wrap can removed or opened by tearing the wrapper

## **Shrink wrapper**

- The shrink wrap concept involves the packaging of the product in a thermoplastic film that has been stretched and oriented during its manufacture.
- An L shaped sealer seals the over wrap
- The major advantage of this type of wrapper are the flexibility and low cost of packaging equipment .

## **BLISTER PACKAGE:**

- Blister package provides excellent environmental protection, and efficacious appearance.
- It also provides user functionality in terms of convenience and resistance and tamper resistance
- The blister package is formed by heat softening a sheet of thermoplastic resin and vacuum drawing the soften sheet of plastic into a contoured mold .
- After cooling the sheet is released from the mold and proceeds to the filling station of the machine. It is then lidded with heat sealable backing material
- Peel able backing material is used to meet the requirements of child resistance packaging.
- The material such as polyester or paper is used as a component of backing lamination.
- Materials commonly used for the thermo formable blister are PVC, polyethylene combinations , polystyrene and polypropylene.

## **STRIP PACKAGE**

- A strip package is a form of unit dose packaging that is commonly used for the packaging of tablets and capsule
- A strip package is formed by feeding two webs of a heat sealable flexible through heated crimping roller.
- The product is dropped into the pocket formed prior to forming the final set of seals. A continuous strip of packets is formed in general.
- The strip of packets is cut into desired number of packets.
- Different packaging materials used are paper/polyethylene/foil/PVC.

## **BOTTLE SEALS**

- A bottle may be made tamper resistant by bonding an inner seal to the rim of the bottle in such a way that the product can only be attained by destroying the seal .
- Typically glassine liners are two ply laminations use in two sheet of glassine paper bounded together with wax or adhesive
- For pressure sensitive inner seals pressure sensitive adhesive is coated on the surface of the inner seal as an encapsulated adhesive.

## **TAPE SEALS**

- It involves the application of glued or pressure sensitive tape or label around or over the closure of the package which is to be destroyed to obtain the product.
- The paper used must often is a high density light weight paper with poor tear strength.

## **BREAKABLE CAPS**

- Breakable closures come in many different designs.
- The roll-on cap design of aluminium shell used for carbonated beverages.
- The bottom portion of the cap is rolled around the bottle neck finish.
- The lower portion of the cap blank is usually perforated to break away when the cap is unscrewed. The bottom portion of the closure has a tear away strip.

## **SEALED TUBES**

Collapsible tubes used for packaging are constructed of metal, plastic or lamination of foil, paper and plastic.

Metal tubes are still used for products that require high degree of barrier protection. Most of these are made of aluminum

Extruded plastic tubes are widely used for products that are compactable and limited protection of plastic.

Thank You!