# PACKAGING MATERIALS

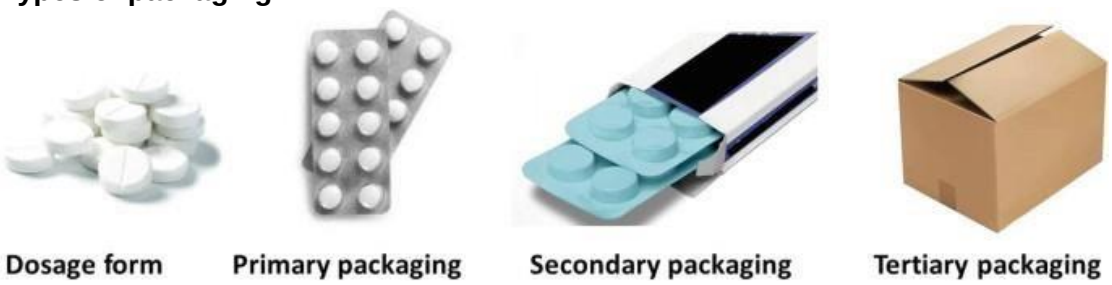
## ❖ Introduction

- 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

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

## ❖ Types of packaging




(i) Primary packaging-
- It 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

(ii) Secondary packaging –
- It is outside the primary packaging perhaps used to group primary package together.
- Ex. Boxes, cartons

(iii) Tertiary packaging-
- It 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

i) Glass
ii) Plastics
iii) Rubbers
iv) Paper/card boards
v) Metals
vi) Cotton/fibres

❖ **The choice of packaging material will depend upon/selection criteria**

(i) The degree of protection required
(ii) Compatibility with the dosage form
(iii) Customer convenience e.g. size, weight of dosage form,
(iv) Filling method
(v) Sterilization method to be employed and cost
(vi) The product or pack contents
(vii) The application of the product
(viii) Content stability, and the need of protection form any environmental factors
(ix) Content reactivity ( with relevant to the packaging material)
(x) Acceptibilty of the pack to the consumer or user
(xi) The packaging process Regulatory, legal and quality issue

**1. GLASS**:

- Glass has been widely used as a drug packaging material
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- Glass is composed of sand, soda ash, limestone,& cullet. Si, Al, Na, K, Ca, Mg, Zn & Ba are generally used into preparation of glass

Advantages

- They are hygienic and suitable for sterilisation
- They are relatively non- reactive
- It can accept variety of closure
- They can be used in high speed packaging lines
- They are transparent.
- They have good protection power.
- They can be easily labelled.
- Economical
- Variety of sizes and

shapes Disadvantages

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

➢ **Types of glass**

- Type I—Highly resistant borosilicate glass or neutral
- Type II—Treated soda lime glass
- Type III—soda lime glass
- Type IV- NP—soda glass (non parenteral usage, genral purpose)

**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 know 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.

**Type III and Type IV glass**

- Both have similar composition and are distinguished from each other on the basis of their hydraulic resistance
- Type III has average or slight better than average resistance and is suitable for non-aqueous parenteral and non parenteral products.
- Type III glass containers are normally dry sterilized before being filled.
- Type IV has lowest hydraulic resistance and is suitable for solid products, some liquids and semi solids and not for parenteral.

| PACKAGE TYPE | TYPE OF FORMULATION CAN BE PACKED | MINIMUM QUALITY OF GLASS THAT CAN BE USED |
|---|---|---|
| Ampoule | Aqueous Injectables Of Any pH | Type I |
| | Aqueous Injectables Of pH Less Than 7 | Type II |
| | Non-Aqueous Injectables | Type III |
| Vial | Aqueous Injectables Of Any pH | Type I |
| | Aqueous Injectables Of pH Less Than 7 | Type II |
| | Non-Aqueous Injectables | Type III |
| | Dry Powders For Parenteral Use (Need To Be Reconstituted Before Use) | Type IV |

| PACKAGE TYPE | TYPE OF FORMULATION CAN BE PACKED | MINIMUM QUALITY OF GLASS THAT CAN BE USED |
|---|---|---|
| Bottles and Jars | Tablets, Capsules, Oral Solids & Other Solids For Reconstitution | Type IV |
| | Oral Liquids (Solutions, Suspensions, Emulsions) | Type IV |
| | Nasal & Ear Drops | Type IV |
| | Certain Types Of External Semisolids (Rubeficients, Local Irritants) | Type IV |
| | Blood & Related Products | Type I |
| Dropper | Auxiliary Packaging Device With Certain Kind Of Products | Type IV |
| Aerosol container | Aerosol product ( solution, suspension, emulsion or semisolid type) | Type I |

## 2. 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**

- Least expensive than glass
- Ease of transportation
- No risk of breakage
- 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**

- They are not as chemically inert as Type-I glass
- Leaching from container to product
- Sorption (absorption or adsorption) of drug molecule or ion on the plastic materials
- They may possess ana electrostatic charge which will attract particle

**Classes of plastics**

There are two classes of plastics, reflecting the behavior with respect to individual or repeated exposure to heating and cooling.

i) Thermoplastics
   - Capable of being shaped after initial heating and solidifying by cooling.
   - On heating they are soften to viscous fluid which harden again on cooling
   - Resistant to breakage and cheap to produce and providing the right plastics are chosen will provide the necessary protection of the product in an attractive containers.
   - E.g. Polystyrene, polyethylene and polyvinyl chloride, Polyethylene{HDPE – LDPE}, Polyvinylchloride(PVC),Polystyrene Polypropylene, Nylon(PA), Polyethylene terepthalate(PET) ,Polyvinylidene chloride(PVdC), Polycarbonate Acrylonitrile butadiene styrene(ABS)

ii) Thermosets
   - They need heat for processing into a permanent shape.
   - When heated they may become flexible but they do not become liquid
   - During heating such materials form permanent crosslinks between the linear chains, resulting in solidification and loss of plastic flow.
   - E.g. Urea formaldehyde (UF),Phenol formaldehyde ,Melamine formaldehyde (MF), Epoxy resins (epoxides), Polyurethanes (PURs)

➢ **Types of plastics**

**Polyethylene**

- This is used as high and low density polyethylene
- Low density polyethylene (LDPE)
  → It is preferred plastic for squeeze bottles.
  → Properties: Ease of processing , barrier to moisture, strength /toughness, flexibility, ease of sealing.
- High density poly ethylene (HDPE)
  → It is less permeable to gases and more resistant to oils, chemicals and solvents.
  → Properties: Stiffness, strength / toughness, resistance to chemicals.
  → It is widely used in bottles for solid dosage forms.
- Drawback: prone to stress cracking in the presence of surfactants or vegetable or mineral oils.

**Polypropylene**

- It has good resistance to cracking when flexed.
- Good resistance to heat sterilization.
- It is colorless, odorless thermoplastic material with excellent tensile properties even at high temperature.
- Excellent resistance to strong acids and alkalis.
- Low permeability to water vapour
- Permeability to gases is intermediate between polyethylene HD and un-plasticized PVC
- Suitable for use in closures , tablet containers and intravenous bottles.

**Polystyrene**

- Versatility, insulation, clarity, easily foamed (“Styrofoam”).
- It is also used for jars for ointments and creams with low water content.
- Drawback: Chemicals like isopropyl myristate produce crazing(a fine network of surface cracks) followed by weakening and eventually collapsible of the container.

**Polyvinyl chloride**

- Versatility , ease of blending, strength / toughness, resistance to grease/oil, resistance to chemicals, clarity.
- Used as rigid packaging material and main component of intravenous bags.
- Drawback: Poor impact resistance which can be improved by adding elastomers to the plastics but it will increase its permeability.

**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:**

- Material strength (capable of withstanding internal pressure in aerosol containers)
- Shatterproof
- Impermeable to gases
- Light barrier (opaque, this is both advantageous and disadvantageous)
- High heat transmission (metals conduct heat well, approximately 100 times better than glass and 400 times better than plastics)
- Mature manufacturing methods
- Malleability, the materials can be tailored in hardness and flexibility to the container
- Dead fold capability (only material with the strength and durability to act as the overcap on vials with elastomeric closure)
- Low weight of finished package (a consequence of the high strength of the material)
- Exterior decoration (both aluminum and tinplate can be highly decorated)
- Tamper evidence (breaking a metal seal cannot be reversed)
- Lightweight (due to the strength of the material in thin cross sections)
- 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:**

- Potential interaction with product (the metal must be coated or
- insulated from the product)
- Limited shelf life (liquids)
- Container weight compared to glass (aluminum containers with density of approximately 2.7 can compete well with plastics; tinplate containers with density over 8 cannot compete against plastics)
- Cost to produce in small unit volumes (this is both advantageous and disadvantageous, depending on container specification)
- Difficulty to produce small volume containers
- Primarily targeted to food products
- 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 and lends itself to high speed automatic filling operations.
- 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.

**4. RUBBER**:

- Elastomers are a group of polymers usually referred to as 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.
- Common rubbers used in pharmaceutical packaging are as follows:
  - → Butyl rubber
  - → Chlorobutyl rubber
  - → Natural rubber
  - → Silicone rubber

i) **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.

ii) **Nitrile rubber**:

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

iii) **Chloroprene rubbers** : Advantages: Oil resistant. heat stability is good.

**iv) Silicon rubbers:**
Advantages:

- Heat resistance.
- Extremely low absorption and permeability of water.
- Excellent aging characteristic. Disadvantages:
- They are very expensive.