PHARMACEUTICAL PACKAGING

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 convenience 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 and shapes

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 that 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 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.

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 charge

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 soften to viscous fluid which harden again on cooling.

e.g. Polyethylene{HDPE – LDPE}, Polyvinylchloride(PVC),Polystyrene Polypropylene, Nylon(PA), Polyethylene terepthalate(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 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.

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 characteristic.

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.
- FDA 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 categorizes 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 bar. 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 , child 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 and 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

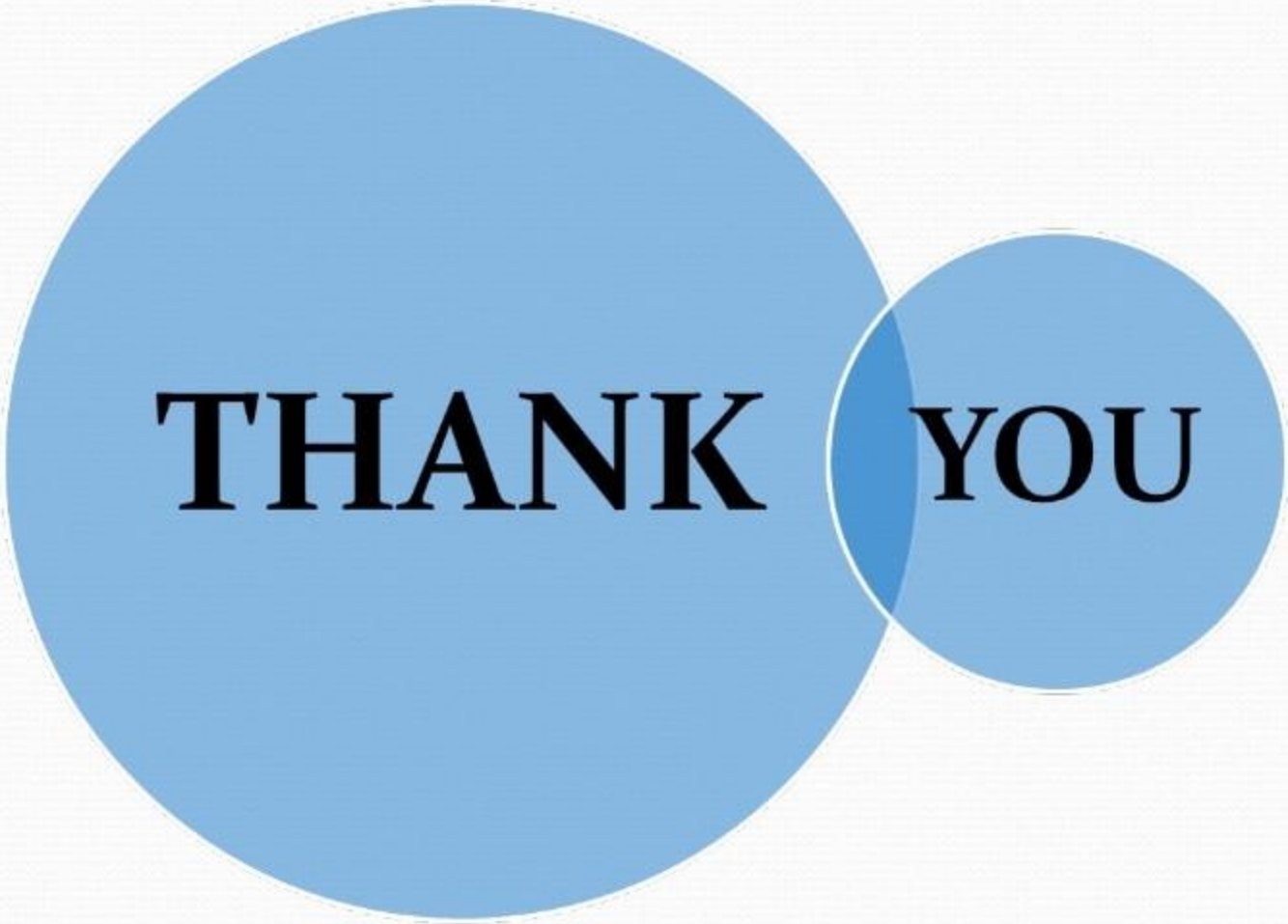
- It involves the application of glued or pressure sensitive tape or label around or over the closure of the package which is to be destroyed to obtain the product.
- The paper used must often is a high density light weight paper with poor tear strength.

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 so that it breaks 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 required 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