

FEATURES, FUNCTIONS AND SELECTION OF PHARMACEUTICAL PACKAGING MATERIALS

Packaging is one of the largest industrial sectors in the world. It is very important in preserving the quality, potency and safety of pharmaceutical products. In the development of packaging material for a particular formulation all the desired tests are to be carried out to ensure its preserving capabilities to maintain the essential characteristics of the formulation during storage. The most commonly used pharmaceutical packaging materials for solid dosage form are glass container, plastic container, paper and paperboard, metal and aluminum foil.

Functions of Packaging Materials



IDENTIFICATION



PRESENTATION



INFORMATION

The pharmaceutical packaging materials contain some important functions like:

- i. Packaging protect against all adverse external influence that can alter the properties of the product,
- ii. Packaging protect against biological contamination,
- iii. Packaging protect physical damage,
- iv. Packaging carry the correct information and identification of the product,
- v. Packaging prevents any wastage (such as leakage or deterioration) which may occur during transportation and distribution, good packaging and presentation encourages consumers to buy products, and good packaging extended the shelf lives of the products.

Selection of the Packaging Materials

The selection of the packaging materials therefore begins with the determination of the products physical and chemical characteristics, its protective needs and its marketing requirements. The material selected must have the following characteristics.

- i. They must not be reactive with products;
- ii. They must be protective from environmental condition,
- iii. They must not be imparted to the products tastes or odors,
- iv. They must be nontoxic,
- v. They must be approved by FDA or other regulatory agencies,
- vi. They must meet applicable tamper resistance requirement,
- vii. They must be adaptable to commonly employed high speed packaging equipment.

CLASSIFICATION OF THE PACKAGING



Types of Packaging Materials

1. GLASS

Glass is generally the first choice of packaging for all types of pharmaceutical products. Glass is the only packaging material 'generally regarded as safe' by the U.S. Food & Drug Administration.

Types of Glass Containers

According to the hydrolytic resistance characteristics, glass containers are classified as follows:

i. Type I glass containers

Neutral glass, with a high hydrolytic resistance due to the chemical composition of the glass.

They can also be used to contain injections or water for injections (in vials and ampoule) strong acids and alkalis (Laboratory glass apparatus)

ii. Type II glass containers

Usually of soda-lime-silica glass with a high hydrolytic resistance resulting from suitable treatment of the surface.

They are used for infusion fluids, blood and plasma. They are used for large volume of containers and containers for eye preparations.

iii. Type III glass containers

Usually of soda-lime-silica glass with only moderate hydrolytic resistance.

They are suitable for non-parenteral preparations.

iv. Type IV glass container

Usually lower-quality flint or soda glass (U.S) or not for parental use.

They are suitable for oral dosage form and topical preparations.

Advantages Glass Containers

- i.** Glass containers are mainly used in packaging liquid preparations due to their rigidity and their superior protective qualities.
- ii.** Its high transparency allows easy inspection of its contents.
- iii.** It offers better protection because it is relatively impermeable to air and moisture.
- iv.** It is chemically resistance to most medicinal products.
- v.** Coloured glass (amber glass and red coloured glass) can protect its content from ultraviolet rays and certain wavelengths.
- vi.** Glass containers can be easily sterilized using heat.

Disadvantages Glass Containers

- i.** Glass containers are expensive to manufacture
- ii.** They are fragile and relatively heavy
- iii.** During heat sterilization, some types of glass containers have the tendency of shedding some part of the silica into the formulation.

2. PLASTIC

Plastics are long-chain polymers that can be melted, formed into a desired shape, and solidified during cooling. They are used for many different types of packs including:

- Rigid bottles which serve as packaging systems for solid dosage forms
- Sterile plastic packaging systems for human blood and blood components
- Plastic packaging systems for aqueous solutions
- Bags for parenteral solutions
- Infusion dry powder and metered-dose inhalers
- Squeezable bottles for eye drops, ear drops and nasal sprays
- Flexible tubes

Advantages of plastic containers

- i.** Plastic containers are not breakable.
- ii.** They are light in weight and resistant to leakage.
- iii.** They are cheap to manufacture
- iv.** They can be easily moulded or re-moulded
- v.** Plastic containers are chemically inert and resistant to corrosion

- vi. They are collapsible

Disadvantages of plastic containers

- i. Plastic containers have poor physical stability due to adsorption, absorption lightness and/or interactions between the formulation and the container
- ii. They have low heat resistant and poor ductility.
- iii. Most plastic containers are usually not as clear as glass, and, therefore, inspection of the contents is impeded.

3. ALUMINIUM

Aluminum is the most abundant metal on the earth's surface, but it is one of the most costly constituents in a laminate. Foil is obtained from metal of 99% purity and above. For solid dosage form (i.e. tablet, capsules, and powders) aluminum foil is the most commonly used packaging material due to its protective characteristics with respect to the effects of moisture, heat and light. Aluminum offers significant saving in the product shipping costs because of their light weight; they provide the attractiveness to the tin at somewhat lower costs.

Important properties of aluminum foil

- i. Barrier**

Alu-foil total barrier to light, atmosphere and liquids is the principle reason for its use in pharmaceutical applications.

- ii. Hygiene and safety**

Alu-foil does not harbor bacteria. It can be supplied in a fully sterile condition. Many suppliers offer Alu-foil packaging materials produced in hygienic 'clean room' facilities.

- iii. Sustainability**

Alu-foil is weight saving, effective and minimizes the amount and diversity of packaging material needed.

Applications of aluminum and plastic as packaging material

- i. Blister packs**

Alu-foil is particularly suitable for blister packs because of the range of mechanical properties available. It can also be combined with other materials like paper or plastics.

- ii. Strip packs**

Strip packs can be produced from Aluminum or in combination with paper or plastics. Strip packs provide economical high barrier performance and can be filled at high speeds on modern, sterile, filling lines.

- iii. Sachets and pouches**

The sensitive nature of most pharmaceutical preparations demands that the packaging provides a perfect barrier to moisture, and often to light. Alu-foil laminated sachets provide an effective packaging solution for many products whether in powder, cream or liquid form.

4. PAPER AND PAPERBOARD

Paper and cardboard is a pillar of traditional packaging materials, consumption of large, wide range of applications, its output accounts for about 45% of the total output value package.

Paper and paperboard must be appropriate strength, wear resistance; easy to clean; excellent shape and fold,; lower prices, and light weight, can reduce transportation costs; easy to handle after use, reuse and recycling of recyclable; paper and cardboard containers are mainly large cardboard boxes, cartons, paper bags, paper cans, paper plates, etc., are widely used.

5. METAL CONTAINERS

Metal is the most adaptable of all the materials used in the packaging; however it is used to dispense only the non-parental medicinal products since it poses the threat of possible shedding of metal particles into the product. Different metals like tin, aluminum and tinfoil are used in pharmaceutical industries. Metals provide superior protection against contamination as they impervious to light, moisture and gases. They are also lighter in weight when compared to most materials.

The collapsible metal tube is an attractive container that permits controlled amounts to be dispensed easily.

- i. **Tin:** Tin containers are preferred for foods, pharmaceuticals, or any product for which purity is an important consideration. Tin is chemically inert of all collapsible tube metals. It offers a good appearance and compatibility with a wide range of products.
- ii. **Aluminum:** Aluminum tubes offer significant savings in product shipping costs because of their light weight. They provide good appearance.
- iii. **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 of lead poisoning. The inner surface of the lead tubes is coated and is used for products like fluoride toothpaste.

6. CAPS AND CLOSURES

They are also known as stoppers or bungs. The primary function of the closure system is to retain or contain the content, safety and security may be necessary to prevent hazards resulting in leakage, seepage, spillage, pilferage, loss of quality, purity, etc.

The materials used for the formation of closures include: Metals like aluminum, aluminum alloys, tinfoil, tin free steel, stainless steel. Glass is used for formation of stoppers. Rubbers and plastics are also and very commonly and widely used for cap and closures.

TYPES OF CLOSURES

The basic types of caps and closures include:

i. Thread Screw

This provides physical and chemical barrier to the contents in the container. They are either made of plastic or made of metal.



ii. Lug Cap

This differs from the thread screw closure due to the presence of continuous thread on the container. It is more commonly used in food industries rather than pharmaceutical industry.



iii. Crown Cap

It is a crimped closure more commonly used in beverage industry.



iv. Rubber Closures

Rubber consists of several ingredients one of which is an elastomer. These closures do not pose any problem and can be used in contact with a large number of drug preparations.



v. Roll on Closure

These are dimension specific. Roll on closure hence require an easy to mould material such as aluminum.

vi. Pilfer Proof Closure

This differs from standard roll on closure in that it has a longer skirt length. When this closure breaks at the bridge, the bank remains at the neck of the container. It requires torque to remove the cap.



vii. Tamper – Evident Closures

Tamper evident closures are designed to prevent accident and intentional tampering to create safe packaging. Various types of tamper evident packaging are used in pharmaceutical industries.



viii. Child Resistant Closures

Child-resistant packaging or C-R packaging is special packaging used to reduce the risk of children ingesting dangerous items. This is often accomplished by the use of a special safety cap. It is required by regulation for prescription drugs, over the-counter medications.

