



“Pharmaceutical Packaging Materials: The Current Scenario And Futuristic Anticipation”

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ABSTRACT- Packaging is a method, that protects the product against the impacts of external gasses, humidity, microorganisms, and bacteria of any kind. In the pharmaceutical industry, packaging has been crucial since it protects the product's integrity in a variety of ways, including by offering display, protection, identity, and information. Pharmaceutical companies are the most innovative when it comes to packaging. The packaging's main objective is to protect and preserve drugs while also giving clients access to legal information and formulations. Containers and closures, which serve as the primary packing materials, are made from a variety of glass, metal, and plastic materials. Therefore, we must pick the components carefully to avoid affecting the product's therapeutic effect. In this review article, we look into the materials, container kinds, and recent packaging innovations in the pharmaceutical sector.

KEYWORDS- Pharmaceutical packaging, Materials for packaging, Closures, Child-resistant packaging.

INTRODUCTION- Packaging is a technique by which a pharmaceutical product is kept secure from the time it is manufactured until it is used¹. Drug encasing is essential for producing items like medical nutritional as well as life-saving drugs, medical treatments, equipment, and processes. Pharmaceutical packaging is a multi-step, intricate process. It is responsible for providing all dosage forms of life-saving drugs, therapies, and cutting-edge goods such as medicinal nourishment². Pharmaceutical packaging requires the careful balancing of many complex aspects. Pharmaceutical packagers have a greater emphasis on crucial problems like preventing replicating, promoting adherence of a patient, ensuring medicine character, & finding a balance between both child safety & accessibility for older people than they do with relatively straightforward problems like producing quality designs & connecting to consumers. Environmental protection is the key issue for packaging companies in industrialized as well as emerging countries³. The latest technological advancements show that pharmaceutical packaging businesses are among the industry's top innovators. The current developments are a result of the issues that the sector continues to face. The Packaging industry is constantly changing & provides a significant influence on how pharmaceutical companies conduct business⁴.

NEED OF PACKAGING-^{5,6}

- To give physical protection to the drug substance.
- To give protection to the drug from outside effects of the environment.
- To give additional protection to the life-saving product.
- To control the dosage form.
- To improve certain physical properties of powders such as bulk density, flow rate, dispersibility, and stability.
- To give an attractive finish to the product.

THE IDEAL PROPERTIES OF PACKAGING MATERIALS- ^{3,7,8.}

- It must be mechanically robust enough to withstand handling, filling, sealing, and shipment.
- It must have an appealing design that makes it simple to extract the contents.
- The things inside of it shouldn't have an impact on it.
- There shouldn't be any alkali leaching from the contents as a result.
- The contents of the container shouldn't be absorbed by the container.
- The container should be made of impartial materials.
- It should be able to endure the heat during sterilization.
- Mold & Fungus shouldn't be able to develop within the vessels.
- There shouldn't be any interaction between the closure or any part of the vessels.
- The cap needs to be non-toxic and chemically inert to the substances in the container.

PURPOSES OF THE PACKAGING- ^{9,10,11,12,13.}

- **Cover from Heat:** A high temperature may speed up reactions and reduce the shelf life of medicinal products. Quality packaging is crucial in shielding goods from these circumstances.
- **Cover from Light:** To stop product from photo-degradation, amber-colored containers might be utilized.
- **Cover from Perspiration & Moist:** Containers should protect the inside materials from moist & perspiration.
- **Cover from Squeezing & Shock:** Adding secondary packing to a product can help it resist squeezing. These packets are created by using cardboard.
- **Cover from Impact:** Product drops result in impact action. By cushioning the primary pack and placing it within the secondary pack, impact damage can be prevented or lessened.
- **Cover from Biological Risks:** Packaging prevents product contamination by microbes.
- **Product's Appearance & Formulation:** The packaging of medicinal products may also provide information. Labels and package inserts include this information for patients.
- **Products Transportation:** Packaging comes in a wide variety, which makes handling diverse sorts simpler.
- **Product Identification:** The purpose of this is to identify the product.
- **Product Protection:** It gives protection to the product from both physical & chemical hazards.
- **Packaging Advantages:** To make it easier to distribute, handle, sell, and consume products and to provide customers more access to them, packaging has to be straightforward.

CLASSIFICATION OF PACKAGING- ^{3,14,15,16.}

- **Consumer Packaging:** The first packaging envelope to contact the dosage form is this one. In order to prevent any interactions with the medication, pharmaceuticals must be adequately enclosed in the container. Exp: Sachet packaging, Blister, Bottles, vials, etc.
- **Group or Display Packaging:** This is the type of packaging that is external to the primary package. The package offers storage conditions & data about the pharmaceutical substance. Exp: Small cardboard cartons, Plastic crates, Shrink-wrapped bundles, etc.
- **Bulk or Transit Packaging:** This will make handling and moving large amounts of medicine from one place to another easier. Exp: Large cardboard boxes, Stretch wrap, pallets, Barrels, etc.

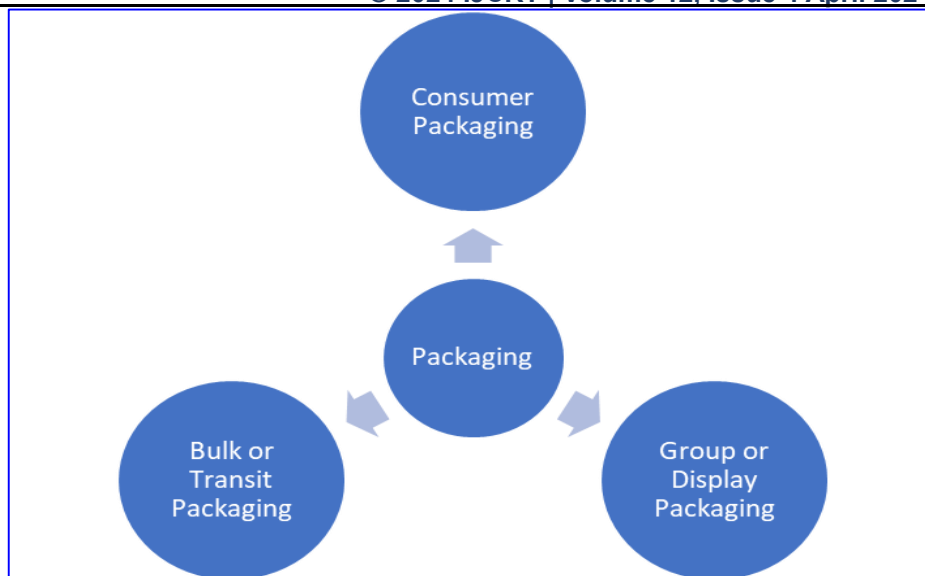


Figure-1: Classification of Packaging.

FOR LIQUIDS, THE FOLLOWING TYPES OF CONTAINERS ARE UTILIZED AS MAJOR PACKAGING-^{8,16.}

- **Single-Unit:** contains the single-use products. Exp-vial & ampules.
- **Multi-Unit:** contains two or more doses. Exp- vial & vitamin tablet bottle.
- **Well-Sealed:** Protect the product against external contaminants and use-related content loss.
- **Hermetic Containers:** Airtight seals are impermeable to solids, liquids, and gases during normal storage and use. They must reclose tightly if it will be opened more than once.
- **Light-resistant:** a container that, due to the special properties of the materials it is built of, including any coating, protects its contents from the effects of light.

FOR SOLIDS, THE FOLLOWING TYPES OF CONTAINERS ARE UTILIZED AS MAJOR PACKAGING-^{16,17.}

- **TEP:** It provides evidence to the end consumer that the product hasn't been tampered with. For the pharmaceuticals this type of packaging is necessary.
- **Unit dose Packing:** A single dose of the product is contained in at least one material pocket that is sealed within a strip of packaging. Two distinct layers of film are used to construct this packaging. These layers composition is determined by way of type and level of safeguard needed by the materials being protected.
- **Bubble Packing:** It consists of the base layer, cover, and chambers that resemble blisters and hold the medication. The base layer and lid are joined by pressure, heat, or by both. They are not utilized for powders or semi-solids and are more rigid than unit dose packages. With the help of an aluminum membrane, it can further give protection against excessive humidity^{18.}
- **C-R Packing/ Special Packing:** It obstructs the child's access to the possibly dangerous item^{19.}

FOR SEMI-SOLID, THE FOLLOWING TYPES OF CONTAINERS ARE UTILIZED AS MAJOR PACKAGING-^{20,21.}

Metal tubes with collapsible ends are used to package ointments, lotions, and other semisolid products. Creams are also contained in plastic packaging. In this a valve is used to release the product from pressured packaging. The amount of force needed to eject the item out of the package becomes a crucial factor when choosing an enclosure for the product.

DEPENDING ON THE PRIMARY COMMODITY-^{22,23,24.}

The materials utilized to make containers & closers are categorized into 4 types:

- **Glass.**
- **Plastic.**
- **Metal.**

- **Rubber.**
- **Paper and paperboard.**

Glass:- These are widely used to store pharmaceutical medications. These packing pieces are made to be in close proximity to medications. These must be stiff, robust, impermeable, and chemically inert. In between 50-60 percent of medications are kept in this ^{3,8,9,25}.

Composition of Glass: 10% calcium oxide, 15% sodium oxide, 75% silica.

According to their Hydrolytic Resistance- ^{3,8,25,26}.

- **Type-I:** Because of the chemical makeup of glass, they're neutral and exhibit strong hydrolytic resistance. It is suitable for all kinds of preparations.
- **Type-II:** They are made up of treated soda-lime glass and have strong hydrolytic resistance. They are employed for neutral and acidic parenteral solutions with pH values less than 7.
- **Type-III:** They have a modest resilience and are composed of ordinary soda-lime glass. They're ideal for aqueous parenteral preparations, parenteral powders, and non-parenteral preparations.
- **Type-IV:** They are composed of soda-lime glass and are not very resistant. They work well for some liquid or semi-solid goods as well as solids that are not intended for parenteral usage.

Tests- ^{21,22,23}.

- Water attack test
- Powdered glass test
- Etched surface test
- Arsenic test
- Light transmission for colored protecting glass containers
- Thermal shock test

Benefits & Drawbacks- ^{23,25,27}.

There are several Benefits & Drawbacks associated with the Glass materials that are used in the pharmaceutical industry, in the below table Some important Benefits & Drawbacks are discussed.

SLNO:	Benefits	SLNO:	Drawback
1)	Because of the transparency, the contents are clearly seen from the outside.	1)	Due of their considerable weight, their transportation costs are higher.
2)	They can be used to create light-resistant glass by mixing them with basic oxides.	2)	It can easily leach alkali into water-based solutions if they are not treated properly using chemical procedures.
3)	In the course of sterilizing, they can tolerate pressure and heat.	3)	They are subject to weathering.
4)	They are available in a wide range of sizes and forms.	4)	They can break easily.
5)	It is simple to label them.	5)	It is more costly than plastic.

Table-1: Benefits & Drawbacks of Glass.

Plastic- These are an assortment of synthetic organic polymers that may be molded, cast, extruded, drawn, or laminated into a variety of shapes. These make up 25% of the total weight of pharmaceutical packaging. These are also the main reasons for hazards so scientists are finding innovative methods to slow down their effects on the environment ^{11,28}.

Composition – Polyvinyl Chloride, Polystyrene, Polyamide, PET, Nitrile polymer, PP, PE ²³.

Types- Plastics come in two different varieties they are: ^{23,25,29}.

- **Thermosetting-** They are no longer able to melt back into liquids or be recycled. Additionally, they have excellent resistance to heat, chemicals, and mechanical force.

- Thermoplastics- They have low melting points, chemical resistance, capacity to preserve molecular structure after heating and reshaping.

Tests-

- Leakage test.
- Collapsible test.
- Clarity test.
- Water vapor permeability test.
- Hydrostatic test.

Benefits & Drawbacks-^{11,23,25,29.}

There are several Benefits & Drawbacks associated with Plastic materials that are used in the pharmaceutical industry, in the below table Some important Benefits & Drawbacks are discussed.

SLNO:	Benefits	SLNO:	Drawback
1)	These are very light in weight.	1)	Stress causes structural abnormalities in them.
2)	They are simply shaped into the required form.	2)	Permeation is the biggest drawback.
3)	These are not prone to alkali leaching like glass containers.	3)	The container material might also absorb preservatives. This may affect the container's flexibility.
4)	These are fairly inexpensive.	4)	Light can penetrate the container and damage light-sensitive medications.
5)	There are many different sizes and forms of them.	5)	Leakage becomes a big problem.

Table-2: Benefits & Drawbacks of Plastic.

Metal- They are commonly utilized in the production of semisolid dosage forms, aerosols, and solid substances. Metals shouldn't be utilized to hold liquid dosage forms because they will react with liquid^{19,30}.

Composition- Aluminium, Tin, Lead²³.

Types- There are mainly 2 types of metal containers are there:^{21,25.}

- Collapsible Tubes- a tube having soft, thin walls that can be bent and collapsed easily. These can be made of aluminum, tin, or lead. They are used in the packaging of semisolid pharmaceuticals.
- Foils- Aluminium is the most commonly utilized material for this purpose. As a result, the containers for pills and capsules are both light and sturdy.

Tests-^{23.}

- Arsenic test.
- Leak test.
- Collapsibility test.

Benefits & Drawbacks- ^{9,21,23,25.}

There are several Benefits & Drawbacks associated with the Metallic materials that are used in the pharmaceutical industry, in the below table Some important Benefits & Drawbacks are discussed.

SLNO:	Benefits	SLNO:	Drawback
1)	These are lighter in weight.	1)	Metal particles may be leached into the medication.
2)	These are stronger among all materials.	2)	Materials with a high reactivity.
3)	These are resistant to light, moisture, and gas.	3)	These are too much costly.
4)	Printing directly on the surface is possible.	4)	These are complex.
5)	Mostly available in round & cylindrical shape.	5)	These can be mostly reactive.

Table-3: Benefits & Drawbacks of Metal.

Rubber- It is generally used in manufacturing as closure. It protects the environment by preventing leaks ^{19,23.}

Composition- Butyl rubber, Chlorobutyl rubber.

Types- It appears in 2 varieties. These are: ^{23.}

- Polyisoprene-They are derived from naturally occurring sources. They are suitable for multi-purpose closures. Natural rubber, on the other hand, hardens when autoclaved and becomes brittle. It also raises the prospect of rubber absorption into the product.
- SBR- They consist of 2-methyl-1,3-butadiene derived products such as polychloroprene or chloroprene, which were utilized to make artificial rubber. We may obtain rubber with the proper shape, strength, capacity, and elasticity depending on the derivatives blend of additives used.

Tests-

- Identification.
- Sterilization test.
- pH of aqueous extract.
- Absorbance.
- Compatibility test.
- Leakage test.
- Finish test.
- Fragmentation test.

Benefits & Drawbacks- ^{19,23,25.}

There are several Benefits & Drawbacks associated with the Rubber materials that are used in the pharmaceutical industry, in the below table Some important Benefits & Drawbacks are discussed.

SLNO:	Benefits	SLNO:	Drawback
1)	These are offered at a very reasonable price.	1)	These are passed through the leaching.
2)	Nature's frailty has no effect on them.	2)	It will transform into liquid at high temp.
3)	It is sufficiently pliable.	3)	Temperature sensitive.
4)	It is easily available in the market.	4)	Sorption may have an impact on it.
5)	It is available in all required shapes.	5)	It was little a bit expensive.

Table-4: Benefits & Drawbacks of Rubber.

Apart from this, there are several types of closers are there, some of which are elaborately discussed below: ^{21,31,32.}

- Threaded Screw-It is used as the main closure in most of the manufacturing units. It forms a durable barrier that keeps dirt, moisture, and other contaminants out while maintaining the threads. Threaded caps are available in standard, JIC, metric, American standard, and other popular thread types.
- Screw-on- These work in the same way as threaded screw caps. These simply require a quarter turn. Screw-on lids are commonly used to keep food.
- Crimp-on-This type of metal cap is commonly found on beverage bottles. These must be opened with an opener. These can never be resealed.
- Roll-on- These are made of aluminum or lacquered tinplate for sealing the bottles with threaded necks. The airtight seal is created by molding the unthreaded cap onto the bottle's neck. These are mostly used in food and pharmaceuticals.
- Pilfer Proof-This excess length continues all the way down to a threaded component that serves as a bridge. When the closure is removed, the bridge collapses, showing the opening.
- Friction Fit -It requires considerable strength to close and open, which adds to the security. In paint cans, a friction-fit stopper is popular.

Paper and Carton board -They are constructed of a web of cellulose molecules derived from wood. There is a continuous rise in the use of packaging materials. To improve its practical qualities when used as the main package, paper is constantly examined, layered, & wrapped with materials like waxy materials, polymers, or lacquer. Papers of many sorts are utilized in packing. Boards are wider than paper, has numerous layers, & have a significant weight for each surface when every feature is merged ^{9,19.}

Types- Carton boards are categorized into: ^{9,33.}

- SUB - It is sturdy, small & adaptable. and it maintains its sturdiness in moist environments. It's a category of carton board primarily constructed using chemical-based fiber that has not been bleached.
- Solid bleached board- They are made up of many layered bleached sulfates.
- FBB-It is also a type used in pharma & food manufacturing companies.
- Whiteboard- This has been created from numerous layers of chemically bleached pulp. Sometimes this is utilized for the carton's inside covering.
- Chipboard-It is mostly used by food and pharmaceutical companies.

- **Fiberboard-** It is also widely used in the pharmaceutical industry. It is of two types: Solid & Corrugated.

Tests- ¹⁹.

- Dimension.
- Thickness.
- Moisture content.
- Burst & Tensile strength test.

Benefits & Drawbacks-

There are several Benefits & Drawbacks associated with the Paper and Carton board materials that are used in the pharmaceutical industry, in the below table Some important Benefits & Drawbacks are discussed.

SLNO:	Benefit	SLNO:	Drawback
1)	It is eco-friendly.	1)	It is not able to hold heavy weight.
2)	It gives more security to the product.	2)	It is not able to handle extreme pressure.
3)	It is recyclable.	3)	It is not water-resistant.
4)	It is easily available in the market & less costly.	4)	It needs more storage space.
5)	It is widely Appropriate for a Variety of Items.	5)	It needs huge investment.

Table-5: Benefit & Drawbacks of Paper and Carton board.

ALTERNATIVE PACKAGING TYPES- ^{17,20,22}.

- **Film wrapper-** a secure translucent film wrapper for a product or container. To open the container and take the goods out, the film has to be ripped.
- **The Shrink film-**The connection between the cap and storage container was sealed by heat or drying. To open the container and take the product out, the seal has to be ripped.
- **Blob seals-**Below the cap, foil is adhered to a container's opening.
- **Tape seal-**All package openings as well as a bottle's cap are covered with paper or foil. In order to open the container and take the product out, the lid's seal has to be destroyed.
- **Sealed tubes-**A tube's mouth is usually sealed, and in order to gain access to the item, the seal has to be broken.
- **Sealed carton-**A carton's flaps must be tightly bound, therefore the goods may only be removed from the package if it is clearly destroyed.
- **Flexible packaging-** In the present-day package climate for a crowded market, flexible packaging is a key packaging alternative. The right packaging is required to safeguard the final products, including food, drink, personal hygiene items, and prescriptions, as well as to prevent harmful chemical interactions that might endanger the user's health. The three most prevalent forms of flexible packaging are the pouch, bubble and strip pack.

PROBLEMS ASSOCIATED WITH PACKAGING MATERIALS- ²³.

- **Permeability-** Migration of gas as well as vapor via packing materials might shorten a drug's shelf life. The passage of vaporized water & oxygen-rich air by the container boundary toward medicine might cause an issue in case dosage form becomes susceptible to oxidation as well as hydrolysis.
- **Leaching-** The majority of plastic containers have one or more small amounts of ingredients added in order to stabilize the material or give it certain properties, and there is a chance that these ingredients

might leech into the medication. When little amounts of coloring compounds are added to the plastics formulation, difficulties may arise. Certain colors have the potential to migrate into parenteral solutions and cause toxicity.

- **Sorption-** During this method, the packing material removes the drug ingredient from the product. Because active compounds are in solution, consuming them can be disastrous. Due to high-potency medicines being administered in small doses, sorption losses can have a significant impact on the therapeutic efficacy of the preparation.
- **Chemical Reactivity-** Some chemicals utilized for plastic preparation undergo chemical reactions against certain pharmaceutical product elements. The recipe's components may occasionally react with plastic. A small amount of chemically conflicting chemicals may impact the size & shape of a container as well as the item.
- **Alteration-** Alteration refers to changes in characteristics of the packing material caused by medicinal products. Permeation, sorption and leaching have the part for changing characteristics of plastic & even contribute to its breakdown.

ENVIRONMENT SUITABLE PACKAGING- ^{34,35,36,37.}

Demand to manufacture sustainable, eco-friendly products is putting a strain on the packaging business, and it has disrupted packaging, one of the most sophisticated areas of the industry. Suitable packaging is a challenging undertaking for firms serving the pharma industry since ecological factors should not jeopardize security & reliability.

FUTURE ANTICIPATION- ^{19,38.}

In response to environmental ethics, patient compliance, and breakthrough drugs, the pharmaceutical business, research, and manufacturing technologies are continually evolving, resulting in significant improvements in packaging and delivery techniques. Increased R&D spending has resulted in the development of large-molecule drugs, some of which are still in research. As a result, there is a higher demand for injectable packing and self-management devices. Packaging Research and Development presented us with novel substances and methods that allow us to increase the longevity of pharmaceutical products. The rise in self-administered treatments necessitates pharmacy research on self-administration packages. Packaging solutions are essential to guarantee that the drug's efficacy is retained, and it should promote compliance with a dose schedule, assuring dosing precision, and being as effective, simple to utilize, and not painful for patients as feasible. Suppliers participating in the self-administration process must provide delivery devices that facilitate medication reconstitution before use, particularly for nonprofessional care ^{19,38}.

RESULT-

Materials used to exhibit, preserve, and contain pharmaceutical items are referred to as pharmaceutical packaging materials. These substances are essential for maintaining the stability, effectiveness, and safety of medications. The main reason for packaging are giving protection, Physical integrity, sealing & containment, Quality control, Regulatory compliances, Aesthetics and branding.

DISCUSSION-

Packaging is a technique by which any company will give protection to their product or invention. It is essential to give protection to the product from the outside atmosphere. This will ensure the integrity, safety & adhering to legal obligations. But some packaging is the main cause of environmental hazards so environment-suitable packaging is necessary to protect the environment that will help to maintain the eco-system.

CONCLUSION-

Packaging is critical in the pharmaceutical sector. The medical product packaging industry is consistently expanding, with a yearly rate of expansion of at least 10% in recent years. The package plays an important function in the safeguarding of medicinal goods. Medicinal items must be labeled from the time they are manufactured until they are used by patients. This additionally offers the recipient insightful data. Environmentally suitable packages that are degradable and easily recycled are becoming more popular. The Food and Drug administration's approval is necessary before releasing a novel package to the marketplace and once authorized, no modification will be done instead of The Food and Drug Agency approval.

ABBREVIATIONS-

- TEP- Tamper Evident Packaging.
- C-R Packing- Child Resistant Packing.
- PET- Polyethylene Terephthalate.
- PE- Polyethylene.
- PP- Polypropylene.
- SBR- Styrene Butadiene Rubber.
- FBB- Folding Boxboard.

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