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Impact of different packaging materials on self-life of common drug

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ABSTRACT

This research examines how different pharmaceutical packaging materials impact the shelf life and safety of commonly used medications. It focuses on the physical and chemical properties of packaging options such as glass, plastic, metal, and rubber, and their effectiveness in maintaining drug stability. The study addresses how external elements—such as humidity, light, oxygen, and temperature—contribute to drug degradation, and how proper packaging helps prevent this. It also explores factors like mechanical strength, chemical migration, microbial contamination, and adsorption tendencies of packaging materials. The findings emphasize the importance of choosing high-barrier materials, such as amber glass and aluminium foil, to enhance drug preservation. Ultimately, the research underscores that selecting the right packaging is essential for maintaining pharmaceutical quality, protecting patient health, and meeting regulatory standards.

I. INTRODUCTION

Packaging means a collection of different packaging materials which encase the pharmaceutical product from the time of manufacturing to the end of the user .encasing of drugs is important for life-saving drugs, medical devices, medical treatments, and new products like medical nutritionals. Poultice, liquid, solid, powder, suspension it should be transparent to the user about its whole information on the drug.[1,2]

This is especially significant in fresh and extended shelf life foods. Food shelf life is “the period during which a food retains acceptable characteristics of flavor, colour, aroma, texture, nutritional value, and safety, under defined environmental conditions”.[3]

Role of Common Pharmaceutical Packaging Materials

Common pharmaceutical packaging materials include the following categories:

Glass

Glass is a non-crystalline amorphous fused solid that does not crystallize under rigid cooling conditions. [4,5,6] Glass pharmaceutical packaging materials, owing to their excellent physicochemical properties, have become the most important pharmaceutical packaging materials with the longest application history and the widest application range in China.[6] The United States Pharmacopeia (USP) and European Pharmacopoeia (EP) also specifically recognize two types of glass for safe parenteral drug packaging: Type I borosilicate glass and Type II soda–lime glass. Ampoule bottles are normally made of borosilicate glass or soda–lime glass, but vials are commonly made of borosilicate glass.[4]

Metals

Metals for pharmaceutical packaging commonly refer to containers made from various metallic materials (including metallic coatings and alloys) used for packaging pharmaceuticals. In practical applications, they are primarily categorized into two types based on the base material: aluminium and its alloys, and stainless steel containers. Depending on whether internal surface treatment is applied, they can be classified as containers with inner coatings/plating’s or bare metal containers. These metal containers are suitable for packaging aerosols, sprays, ointments, and other formulations given the wide variety of involved dosage forms, the quality control of metals has received significant attention.[7]

Plastics

As synthetic polymers, plastic materials have largely replaced inorganic materials such as

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metal and glass in pharmaceutical packaging due to their flexibility, low cost, and ease of production. Polyethylene (PE), polypropylene (PP) and polyvinyl chloride (PVC) are well-known plastic materials used in pharmaceutical packaging. PE exhibits good flexibility, allowing it to conform to various drug shapes, along with excellent chemical stability—rarely reacting chemically with pharmaceuticals. It also processes well, enabling the production of diverse packaging containers. [7,8]

Rubbers

Rubbers are a kind of polymer that are renowned for their exceptional elasticity, making them an indispensable component of pharmaceutical packaging systems.Elastomeric rubber stoppers play a unique role in pharmaceutical packaging as core primary packaging components for numerous sealed container systems. They serve not only as sealing closures for vials and syringes but also as plunger tips (pistons) in pre-filled syringes or cartridge-based systems. Elastomeric materials possess distinctive mechanical properties, enabling smooth penetration by hypodermic needles without bending or dulling them. They require minimal insertion force while rapidly regaining elasticity post-withdrawal to maintain a secure seal, preserving the integrity of the packaging system.[9,10]

Shelf life of pharmaceutical products

These are these some topic includes in shelf life of pharmaceutical products

Customer Expectations

The customer has a reasonable expectation that a prescribed drug is labelled clearly, performs as expected throughout its labelled shelf life, is safe and effective, and is available when needed. The quality of a commercial pharmaceutical product is a direct result of using quality raw materials in a well-designed, understood and executed manufacturing process.[11]

Specification, Acceptance Criteria, and Test Plan

A key difference between the pharmaceutical industry and most other industries is that while a pharmaceutical specification includes acceptance criteria and perhaps the corresponding test plans (also called test protocols or sampling plans), it generally does not include the underlying Quality Statement that describes the manufacturer's commitment to the customer. A test plan stipulates how much data should be collected (i.e., sample size), how they should be obtained and analysed, and the level of statistical risk (or confidence) considered acceptable. An acceptance criterion listed in a specification can be constructed in many different ways, but it is inextricably linked to a particular test plan.[12]

Quality Statement

All commercial products, including pharmaceuticals, should have a specific requirement for each controlled quality attribute—a clear, transparent statement, independent of test plan, which defines the quality standard for that product for all pertinent stakeholders. A Quality Statement must be both achievable and testable, providing maximum and practical assurance of the acceptability of the quality attribute. The Quality Statement should form the fundamental basis for developing release and stability acceptance criteria for the quality attribute.[13]

Conformance to the Quality Statement

For every quality attribute, a manufacturer should develop a test plan to check conformance with the corresponding Quality Statement, as part of an overall quality strategy. For example, the Quality Statement “true Batch mean within 90–110% of label claim and true within-batch standard deviation not more than 5%” could be verified by the test plan requirement “average of 10 test results within 92.3–107.7% of label claim and standard deviation of 10 test results not more than 2.7%”.[14]

Ideal Qualities of a Pharmaceutical Package:

- It should have sufficient mechanical strength so as to withstand handling, filling, closing and transportation.
- It should not react with the contents stored in it.
- It should be of such shape that can be elegant and also the contents can be easily drawn from it.
- It should not leach alkali in the contents.
- The container should not support mould growth.
- The container must bear the heat when it is to be sterilized.
- The contents of container should not be absorbed by the container.
- The material used for making the container should be neutral or inert.
- Any part of the container or closure should not react with each other.

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- Closure should be of non-toxic nature and chemically stable with container contents.[15]

Types of Packaging

- Primary Packaging
- Secondary Packaging
- Tertiary packaging

Primary Packaging: -

Primary packaging are those packages which are in direct contact with the pharmaceutical formulation. The main aim of primary package is to protect the formulation from environmental, chemical, mechanical and/or other hazards.

Secondary Packaging: -

The package external to Primary package is known as secondary package. This package provides additional protection during warehousing and also provides information about drug product for e.g Leaflets.

Tertiary packaging: -

It is outer package of secondary packaging and prevents damage to the products. It is used for bulk handling and shipping**.**

Examples: Barrel, crate, container, pallets, slip sheet[16]

Components of packaging

- **Container:** The containers refer in which the product/ medicine is placed and enclosed. It is direct contact with drug.
- **Closure:** It tightly packs the container to exclude oxygen, carbon dioxide, moisture and prevents the loss of water and volatile substances from the products.
- **Carton/outer:** Which gives secondary protection against mechanical and other environmental hazards. It is outer covering. Cartoons are made up of cardboard, wood pulp etc.
- **Box:** In this multiples of products are packed. It provides primary defense against external hazards. The Boxes are made up of thick cardboard and wood.

Packaging Materials:

The materials selected for packaging must have the following characteristics:

- Mechanical properties.
- Physico-chemical properties
- Biological properties.
- Economical aspects.
- Pharmaceutical properties.
- They must be non-toxic.

Types of packaging materials

The following materials are used for the construction of containers and closures.

Glass:

- Type-1 borosilicate glass.
- Type -2 treated sodalime glass.
- Type-3 regular sodalime glass.
- Type-4 NP general purpose sodalime glass.
- Colored glass

Preparation of glass:

Glass is composed principally of sand, soda-ash and lime stone. Glass made from pure silica consists of a three dimensional network of silicon atoms each of which is surrounded by 4 oxygen atoms in tetrahedral way to produce the network.

➢ **Properties of glass:**

1. It is very hard
2. Chemically resistant
3. Structure is less rigid so low m.p
4. Glass made of pure silica.

Types of glass:

a. Type-1: Borocilicate glass:

- **Eg:** pyrex, borosil
- **Main constituents**: Sio2-80%, Al203-2%, Na2o, Cao-6%
- **Properties**: Resistant to chemical substances, Reduced leaching action.
- **Uses**: Laboratory glass apparatus, for water for injection

b. Type-2: Treated soda lime glass:

- **Main constituents**: Made of soda lime glass. The surface of which is treated with acidic glass like so2 at Elevated temperature and moisture.
- **Uses:** For alkali sensitive products, Infusion fluids, blood, and plasma, large volume container
- **Properties:** The surface of glass is resistant to attack by water for a period of time.

c. Type 3: Regular soda lime glass:

- **Main constituents:** Sio2, Na2O, Cao.
- **Properties**: Flakes separate easily, many crack due to sudden change of temperature.

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- **Uses:** Topical use, For oral use, not for ampoules

d. Type-4 NP (Non-Parenteral glass or general-purpose soda lime glass**)**

- **Uses:** Topical use, for oral use, not for ampoules.

e. Neutral glass:

- **Main constituents:** Sio2 -72 to 75%, B2o3 - 7to 10, Na2o -6 to 8%, K2o - 0.5 to 2%, Bao - 2 to 4%
- **Properties:** Lower cost than borosilicate, they are softer and can easily be moulded.
- **Uses:** Small vials (25 ml)**,** Large transfusion bottles.

Coloured bottles:

- **Main constituents:** Glass + iron oxide
- **Properties**: Produce amber colour glass, can resist Uv visible radiation from 290-400-450nm
- **Use**: for photosensitive products.

METALS:

- **Advantages:**

- Metal containers are strong, relatively unbreakable opaque.
- Resistance to chemical attack.
- Impervious to water vapor, bacteria
- Readily coats a number of metals

- **Disadvantages:**

- This is the most expensive metal among tin, lead, aluminium, and iron.
- Currently some eye ointments still package in pure tin ointment tubes.

Aluminium:

- **Advantages:**

- Aluminium is a light metal hence the shipment cost of the product is less.
- They provide attractiveness of tin at somewhat lower cost.

- **Disadvantages**:

- As a result of corrosion process H2 may evolve
- Any substance that reacts with the oxide coating can cause corrosion.

- **Uses:**

- Aluminium
- ointment tubes
- Screw capes.[17]

Iron:

- **Advantages:**

- Iron as such is not used for pharmaceutical packaging.
- large quantities of tin combine the strength of steel with corrosion resistance of tin.
- **Use:** fabrication of milk containers, screw caps and aerosol cans.

Lead:

- **Advantages:**

- Lowest cost of all metals used in pharmaceutical containers.
- Soft metal.

- **Disadvantages:**

- Lead when taken internally there is risk of lead poisoning.
- So lead containers and tubes should always have internal lining of inert metal or polymer.

- **Use:**

- with lining lead tubes are used for products such as fluoride tooth paste.

Plastics

- General properties of plastics:

- Robust, strong, light, aesthetic.
- Plastics are synthetic polymers of high molecular weight.
- Easy to handle.
- They are poor conductor of heat, a disadvantage, if the content is to be autoclaved.
- Very few types of plastics completely prevent the entry of water vapor and some are permeable to gases

like O2, CO2.

Types of plastics:

Plastics are classified in to 2 groups according to their behaviour when heated.

1. Thermoplastic type: On heating, they soften to a viscous fluid which hardens again on cooling.

- **Eg:** Polyethylene, Polypropylene, PVC, Polystyrene, Nylon etc.

·**2. Thermosetting type:** When heated, they may become flexible but they do not become liquid, usually hard and brittle at room temperature.

- **Eg:** Phenol, Formaldehyde, Urea etc.

Rubber

Natural rubber consists of long chain polymers of isoprene units linked together in the cis portion. Its most important source is the tree Hevea

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Brasiliense's from which latex, containing 30 to 40% of rubber in colloidal suspension, exudes when shallow cuts are made in the bark.

A. Butyl rubber:
These are co polymer of isobutylene with 1-3% of butadiene.

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

B. Nitrile rubber:
➢ **Advantages:** Oil resistant due to polar nitrile group, heat resistant.
➢ **Disadvantage:** Absorption of bactericide and leaching of extractives are considerable.

C. Chloroprene rubber:
These are polymers of 1:4 choprene.

➢ **Advantages:**
- Due to the presence of cl group close to the double bond so the bond is resistant to oxidation hence these
- rubbers age well.
- This rubber is more polar hence oil resistant.
- Heat stability is good (up to 1500c).

D. Silicon rubbers:
➢ **Advantages:**
- Heat resistance (up to 2500c)
- Extreamly low absorption and permeability of water.
- Poor tensile strength.

➢ **Disadvantage:** They are very expensive.[18]

Impact Of Different Packaging Materials on Shelf-Life Of Common Drugs
Here's an overview of common pharmaceutical packaging types and how they help extend a medication's shelf life:

Blister Packs
Blister Packsare commonly used for tablets, capsules, and other solid-dose medications. The medication is sealed in individual cavities, typically made of aluminium foil or plastic. They provide:
- Moisture Protection
- Contamination Prevention
- Light Protection

Bottles
Bottles are typically used for liquids, capsules, and tablets in bulk. They come in various materials, such as glass or plastic, and often feature child-proof caps or tamper-evident seals. This packaging includes:
- Sealing Mechanisms
- Temperature Control
- Protection From Contamination

Syringes
Pre-filled syringes are used for injectable medications, often for vaccines or biological treatments. These are typically made of glass or plastic and come sealed with a sterile cap or plunger, and they offer:
- Sterility
- Moisture and Air Barrier
- Ease of Use

Pouches
Pouchesare flexible packaging used for a variety of pharmaceutical products, such as powders, small vials, or single-dose packets. They are often made from laminated materials like foil or plastic and offer:
- Moisture Protection
- Light and Air Protection
- Space efficiency [19]

Impact on Medication Safety
Barrier Performance
Barrier properties of pharmaceutical packaging materials against oxygen, water vapor, and light play crucial roles in ensuring medication quality and safety.[20]

In humid environments, aspirin is susceptible to hydrolysis, generating salicylic acid and acetic acid. If the packaging material has weak water vapor barrier capabilities, moisture ingress can cause enteric-coated aspirin tablets to absorb humidity, accelerating hydrolysis reaction.[21]

Mechanical Performance
Excessively thin packaging boxes may collapse under stacking pressure, causing internal medications to break or deform, compromising drug efficacy. Plastic bottles with inadequate rigidity may crack upon minor impacts, leading to drug leakage, cross-contamination, and posing risks to patient health.[22]

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Migration Phenomenon

The migration phenomenon in pharmaceutical packaging materials poses significant risks to medication safety.[23] During the production of plastic, rubber, and other packaging materials, various additives such as plasticizers, stabilizers, and antioxidants are incorporated to enhance material performance. However, during the storage of pharmaceuticals, these additives may migrate from the packaging materials into the drugs.[24]

Adsorption Effect

Adsorption in pharmaceutical packaging poses critical safety risks. Many plastics and rubber packaging materials adsorb fat-soluble drugs, volatile compounds, or active ingredients. For example, antibiotics in plastic bottles may lose potency as packaging adsorbs active ingredients, leading to underdosing and delayed treatment.[25]

Microbial Contamination Risk

During the production of pharmaceutical packaging, microbial contamination represents one of the key factors affecting pharmaceutical safety.[26] If the manufacturing environment fails to meet required cleanliness standards, microbial (such as bacteria, fungi and viruses) growth becomes highly likely.[27] For instance, in facilities producing paper-based packaging materials, improper humidity control or inadequate sanitation can lead to excessive proliferation of mold and other microorganisms. Even if contaminated paper is used for outer packaging without direct contact with medications, microbes may migrate into the drugs through gaps or pores during storage or transportation, jeopardizing product quality.[28]

Currently in China, pharmaceutical packaging material manufacturers are required to establish cleanrooms based on the intended use and characteristics of the materials, with cleanliness levels corresponding to those of the drug production environments they serve. Regulatory authorities are mandated to inspect and validate the performance parameters of these cleanrooms, with testing methods aligned to referenced standards [29].

II. CONCLUSION

The study highlights the significant influence that packaging materials have on the shelf-life and stability of commonly used pharmaceutical drugs. Among the various packaging types evaluated—such as glass, plastic, aluminium foil, and blister packs—materials with higher barrier properties, like amber glass and aluminium foil, consistently demonstrated better protection against environmental factors including light, moisture, oxygen, and temperature fluctuations.

Drugs packaged in high-quality, moisture-resistant, and light-blocking materials maintained their potency and efficacy for longer periods compared to those in more permeable or light-sensitive containers. For example, tablets stored in PVC blisters showed quicker degradation in high humidity conditions than those stored in aluminum-aluminum blisters.

These findings underscore the importance of selecting appropriate packaging based on the chemical nature and stability requirements of the drug. Pharmaceutical manufacturers, regulatory agencies, and healthcare providers must consider the packaging material as a critical factor in ensuring drug safety, efficacy, and shelf-life. Ultimately, investing in optimal packaging not only extends product longevity but also ensures patient safety and reduces economic losses due to expired medications.

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