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Article · January 2018

DOI: 10.5958/0975-4377.2018.00005.8

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WORLD JOURNAL OF ADVANCE HEALTHCARE RESEARCH

ISSN: 2457-0400
Volume: 2.
Issue: 1.
Page N. 16-21
Year: 2018

Review Article www.wjahr.com

PHARMACEUTICAL PACKAGING TECHNOLOGY: A BRIEF OUTLINE

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Received date: 15 November 2017 **Revised date:** 06 December 2017 **Accepted date:** 27 December 2017

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ABSTRACT

Packaging is designed to contain a product so that it is unable to interact with the environment. Packaging must provide the protection, identification, information against the physical damage, loss of content or ingredients and intrusion of unwanted component of the environment such as water vapour, oxygen and light. An important role of pharmaceutical packaging is to transform the formulation into an attractive and marketable product. So many issues regarding the pharmaceutical product like stability, sale, patient compliance etc are related with the packaging and in regard to this; present review is done on the various advancements in the packaging techniques and selection of packaging material, machinery & labelling. The present article reviews the various packaging materials,types of packaging in pharmaceutical industry.

KEYWORDS: Packaging, Protection, Materials, Machinery, Labeling.

INTRODUCTION

Packaging

A Pharmaceutical Package container is an article or device which contains the Pharmaceutical Product and the container may or may not in direct contact with the product. The container which is designed for pharmaceutical purpose must be stable.[1]

Ideal Qualities of a Pharmaceutical Package[2]

1. It should have sufficient mechanical strength so as to withstand handling, filling, closing and transportation.
2. It should not react with the contents stored in it.
3. It should be of such shape that can be elegant and also the contents can be easily drawn from it.
4. It should not leach alkali in the contents.
5. The container should not support mould growth.
6. The container must bear the heat when it is to be sterilized.
7. The contents of container should not be absorbed by the container.
8. The material used for making the container should be neutral or inert.
9. Any part of the container or closure should not react with each other.
10. Closure should be of non toxic nature and chemically stable with container contents.

Types of Package[3]

1. Primary Packaging

Primary packaging are those package 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.

2. Secondary Packaging

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

Functions

- Protect the flexible containers.
- Protection from tough handling during transportation.

3. Tertiary packaging

Examples: Barrel, crate, container, pallets, slip sheet.

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

Components of packaging[3,4]

1. **Container:** The containers refer in which the product/ medicine is placed & enclosed. It is direct contact with drug.
2. **Closure:** It is tightly packs the container to exclude oxygen, carbon dioxide, moisture & prevents the loss of water and volatile substances from the products.
3. **Carton/outer:** Which gives secondary protecion against mechanical and other environmental hazards. It is outer covering. Cartoons are made up of cardboard, wood pulp etc.
4. **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 consruction of containers and closures.

1. Glass

a. Type-1 borocilicate glass.
b. Type -2 treated sodalime glass.
c. Type-3 regular sodalime glass.
d. Type-4 NP general purpose sodalime glass.
e. 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 dimentional network of silicon atoms each of which is surrounded by 4 oxygen atoms in tetrahedral way to produce the network.

Properties

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

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

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, & plasma, large volume container.
- **Properties:** The surface of glass is resistant to attack by water for a period of time.

Type-3: Regular soda lime glass

- **Main constituents:** Sio2, Na2O, Cao.
- **Properties**: Flakes separate easily, many crack due to sudden change of temperature.
- **Uses:** Topical use, For oral use, Not for ampoules.

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

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

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 & can easily be moulded.
- **Uses:** Small vials (25 ml), Large transfusion bottles.

Colored bottles

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

2. METALS

Advantages

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

Disadvantages

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

Aluminum

Advantages

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

Disadvantages

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

Uses: Aluminum ointment tubes, Screw capes.

Iron

Advantages

Iron as such is not used for pharmaceutical packaging, large quantities of tin combines 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 poisioning. 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.

3. 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 behavior when heated.

- **Thermoplastic type:** On heating, they soften to a viscous fluids which hardens again on cooling. **Eg:** Polyetyline, Polypropylene, PVC, Polystyrene, Nylon etc.
- **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.

4. 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 braziliensis 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.

Labeling[5,6,7]

Definition: Labelling is the term used in the pharmaceutical industry. It is the information that appears on a bottle or package. It gives the best information about a drugs quality, efficacy and safety. The term labelling designates all labels and other written, printed or graphic matter upon or in any package or wraper in which it is enclosed. The label states that a name of the preparation, percentage content of drug of a liquid preparation, the volume of liquid to be added to prepare an injection or suspension from a dry preparation, the route of administration, a statement of storage condition and expiry date. Also indicate the name of manufacturer or distribution.

Types of labels

Various materials are used for labelling such as paper, foil and fabric. It is also possible to print directly on a bottle or other containers by means of silk screen or hot transfer process. Choice will depend on need and economy.

1. Paper labelling

Most labels are printed on paper, since it is the most economical method, whether the quantities are large or small. There is limit to the colours and techniques that can be used in case of paper label.

2. Foil labels

It is nearly always necessary to liminate foil with paper so that the label will work properly in the labeling machines. The foil and paper together should measure 0.0025 to 0.003 inch for best results.

3. Transfer Labels
There are several processes for transferring heat sensitive inks from a pre-printed strip to the container that is to be decorated. These are known by the trade names of
a. Therimage
b. Electoral

4. Sleeve Labels
There are the two types of sleeve labels
1. Stretch band and
2. Shrink tubing

Method of Applying a Label
1. Hot Melts
A simple method of applying a label to a package is with a pasting out board. Glue is put on the board with a brush and the labels are laid face up on the glue. They are manually removed and placed on the containers.

2. Semi Automatic Labelling
With this method the operator places the container in position and the machine applies the label. The speed of the operation is usually dependent upon how fast the operator can remove the container and put a new one in its place. About 3600 per hour is the maximum ideal condition.

3. Fully Automatic Labelling
Glue is applied to the bottle by a rubber pad, often which the label paper of labelling. Bottle and back again leaving a label adhering to the bottle, pressure station complete the operation of labeling.

MACHINERY FOR PACKAGING[4,6,8,9,10]

The machinery is an important techniqe for packing the any medicines or other materials.

1. Strip packing machine

Figure 1: Strip packing machine.

Application
This model is applied for the packing of tablets, candy and pills in medicine, healthcare, chemical, and foodstuff industry etc with automatic double-aluminum foil hot sealing. Meeting the requirement of sealing for avoiding light, and also it is for double plastic hot sealing packing.

2. Blister Packing Machine

Figure 2: Blister Packing Machine.

It is high quality machine, which are suitable for handling automatic loading, filling or none stop feeding. Blister packaging machines are used by pharmaceutical industry to pack capsules and tablets. The packing process initiates with the capsules or tablets being loaded in to a hopper and then in to a feeder which in turn can either be linear feeder or a brush box feeder depending on the shape of the product and also the material to be used.

Applications
- Unit dose hospital packs.
- Ampoule& vial tray packs
- Multi product and child resistant blister packs.

3. Cartoning Machine

Figure 3: Cartoning machine.

Description
This machine is applied to automatically box packing for medicine board, medicine bottle, soft box with palletized granule and ointment. Such as automatically boxing package of medicine, cosmetics. This machine features stable performance, compact structure and beautiful

appearance. And it can automatically print stainless steel stamp. It has multi-function identification system. Automatically stopping or elimination when no tablets or vials are available. Cartoners have an output ranging 30 to 300 cartons per minute depending on whether the machine is vertical loading, intermittent cartoning or a continuous motion model. These machines can handle blister stripes & other pharmaceutical packing.

4. Ampoule Filling Line

Figure 4: Ampoule filling machine.

Description

These high precision machines completely encase the product in the inert glass & don not have a rubber stopper or any other material in direct contact with the drug. The line can be applied to fill 1-20ML ampoule with automatic procedures as follows: Ultrasonic washing, three times water washing (twice circulating water washing, plus one time fresh water washing), three times air spraying, drying and sterilizing, cooling, liquid filling and protection gaseous filling (compressed air filling and nitrogen filling).

5. Liquid Filling Machine

Figure 5: Liquid filling machine.

Description

It features advanced control system, accurate filling, stable performance, excellent appearance.

1. Ideal equipment for filling liquid injection and lyophilization injection.
2. Imported peristaltic pump system has high filling accuracy.
3. Completely 100c purifying laminar flow protection.
4. With function of stop filling without vial.
5. It can automatic count the filled vials.

6. Syringe Filling Machine

Figure 6: Syringe filling machine.

These machines are high precision & reliable machines used to fill syringes, cartridges and other related containers. Filling is done with the help of rotary piston pumps. The machines format spectrum can range from 0.2 to 29ml.

1. Semi automatic syringe filling machine: These machines require manual operators for loading the syringes in to the machine which are then filled & capped automatically. Applications include oral dosage syringe& dental gels.
2. Fully automatic syringe filling machine: These high speed and compact machines automatically fill and are used for saline flush syringes, dental gels and oral dose syringe.

8. Automatic Labelling / Gumming / Stickering Machine

Figure 7: Automatic labeling machine.

Description

- Fully Automatic Labeling machine is useful to place label accurately on round shape of product.
- Full /partial wrap labeling can be possible. A unique feature of machine is if the body diameters changes, than also machine operates without change part.
- Labeling speed is automatically synchronized with conveyor speed to ensure quality.

Pharmaceutical Printing Machine

Figure 8: Pharmaceutical Printing Machine.

Description

This machine is suitable for printing labels, batch number, validity time and series numbers on the surface of cartons, tissue paper, non-ferrous plastic film and aluminum film. No matter with the dry-ink roller or instant liquid ink, it has the features of instant printing and instant drying, and strong adhesion.

CONCLUSION

In recent decades pharmaceutical packaging technology is an important techniqe in pharmaceutical industry. After formulation, the next step is packaging. It is an important process in pharmaceuticals because it provides the protection for products, identification & protection against the physical damage and also gives the attractiveness for the products & improves the patient compliences. Some other better reserches are going on the packaging for better results and pharmaceutical companies increasingly are working to improve productivity and reduce costs in their manufacturing and packaging operations, it gives the good quality of packs & good sales & also economical results. Expanding markets and innovative marketing strategies have led to an increased demand in packaging products.

CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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