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Pharmaceutical Packaging Technology-A Review

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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.

Keywords: Packaging technologies, Pharmaceutical packaging, Materials, Machinery, Labeling.

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1. Introduction

Packaging is the science and technology of enclosing or protecting products for distribution, storage, sale and use. It also refers to the process of design, evaluation, and fabrication of packages. Packaging is defined in the regulations as "all products made of any materials of any nature to be used for the containment protection, handling, delivery and preservation of goods from the producer to the user or consumer." The importance of packaging & labelling is to improve the patient safety, compliances & efficacy.

Packaging System:

Different types of packaging systems are used. For example a transport package or distribution package is the package form used to ship, store & handle the product or inner packages. Consumer package is one that is directed toward a consumer or householder.

Different types of packaging systems

1. Primary packaging

2. Secondary packaging
3. Tertiary packaging.

1. Primary packaging:

Exmples: Aerosal spray, wrappers, Beverage can, bags in boxes, Plastic bags, skin packs, Tin can, blister packs, Envelopes, wine box Primary or sales packaging which forms a sales unit for the user or final consumer, for e.g.; a box containing soap powder. Primary packaging material should not be adversely affected by product and should not be influenced by adverse manufacturing condition (sterilization, freezing).

2. Secondary packaging:

Example: Boxes, cartons, shrink-wrapes

It is outer package of primary packaging. Secondary or grouped packaging is that which contains a number of sales units, for eg: a cardboard containing a number of boxes of soap powder.

Functions:

1. Protect the flexible containers.
2. 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:

- a. **Container:** The containers refer in which the product/ medicine is placed & enclosed. It is direct contact with drug.
- b. **Closure:** It is tightly packs the container to exclude oxygen, carbon dioxide, moisture & prevents the loss of water & volatile substances from the products.
- c. **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.
- d. **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 fallowing materials are used for the consruction of containers and closures.

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

Metals: Tin, Iron, Aluminium, Lead

Plastic

- a. Thermosetting resins
- b. Thermoplastic resins

Rubber

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: Borosilicate glass:

Eg: pyrex, borosil

Main constituents: SiO₂-80%, Al₂O₃-2%, 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.

Advantages:

Physical aspects:

- They are quite strong and rigid, non corrosive
- They are available in various shapes and sizes visually elegant containers attracts the patients.
- Glass containers can be easily cleaned without any damage to its surface.eg: scatching.

Chemical aspects:

- Borosilicate type of glass is chemically inert treated sodalime glass has a chemically inert surface.
- They are cheaper than other packaging materials.
- Photosensitive drugs may be saved from uv-rays by using amber colour glass.

Disadvantages:

Physical aspects:

- They are brittle and break easily.
- They are heavier in comparison to plastic containers.
- They may crack when subject to sudden changes of temperature.
- It imparts an odour and taste to the product.

Chemical aspects:

- Flaking
- Wethering

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:

- a. 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 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.

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.

1. Thermoplastic type: On heating, they soften to a viscous fluids 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.

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 chloroprene.

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 150°C).

D. Silicon rubbers:

Advantages:

- Heat resistance (up to 250⁰c)
- Extremely low absorption and permeability of water.
- Poor tensile strength.

Disadvantage: They are very expensive.

Labeling

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 wrapper 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. Paper labels can be di cut or guillotine cut.

2. Foil labels:

It is nearly always necessary to liminate foil with paper so that the label will work properly in the labelling 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

Tools cost are nominal and the equipment for transferring the label to the container is relatively inexpensive. The operating temperature at the die is around 35⁰f with pressure between 100-200 psi, depending on the size of the label.

4. Sleeve Labels

There are the two types of sleeve labels

1. Stretch band and
2. Shrink tubing

Two-mil low-density polyethylene film is used for stretch type labels. Heat shrinkable labels are made of 3-mil polyvinyl chloride film. They can be applied by hand or with automatic equipment.

Adhesives:

1. Cold Glue:

The lowest cost glue is the starch or dextrin types. They are fairly fast drying but they are not waterproof or ice proof when immersed. Dextrins are usually brown in color, generally acid in reaction. Jelly gums are ideally used in the pharmaceutical industry, and they work well under adverse conditions of hot, oily or wet containers. They are white to reddish brown in colour. Animal glues are used to some extent for beverage bottles because they have good resistance immersion in ice water. They are medium brown in colour. Also it has a good drying speed. Most problems are caused by using too thick a film or glue than by almost anything else. A too thin film hardly ever trouble.

2. Pressure Sensitive

For a clean operation with quick change over, easy in printing and low cost equipment, Although the cost of the labels are higher than for other types, the machines for applying them are only about half the cost of cold glue and heat seal labels.

Disadvantages

- a. Slow speed.
- b. Labels cannot be soaked off easily.
- c. High label cost.
- d. Inaccurate placement of labels.
- e. Poor resistance to oils and solvents.

Heat Seal Coatings:

There are two types of heat activated coatings that are used on labels. The first type is sealed directly to the object with heat and pressure. As soon as adhesive cools, it becomes hard. The second type, which is more often used for bottle labels, is softened by heat and remains soft for a considerable period of time.

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 labelling.

Standard Requirements for Labeling Dispensed Medicines:

All labels must be type written or computer generated. The details, which must appear on the label of a dispensed medicine and other details. It is useful information to patients.

- The name of the preparation.
- Instructions for the patient.
- The patient name.
- The quality.
- The date of dispensing.
- The name and address of the pharmacy.
- Keep out of reach of children.
- Expiry date.

Cautions in use:

The following information may be written on the label in order to caution a patient about certain unusual happenings after taking the medicine.

1. Avoid exposure of skin to direct sunlight.
2. The preparation, which may produce unusual effect.
3. The preparation may colour the urine or stool.
4. Keep away from naked flame.

Abbreviated titles used In Label:

Each abbreviation is in two or more parts. The first part is usually a shortened version of the name of the disease or casual organism. Where only one disease or organism if relevant, three

Ex: Dip for Diphtheria but Flu for influenza and Typhus is unabbreviated.

Labeling For Different Dosage Form:

1. Labeling Ointment Tubes:

It is difficult to attaching labels to ointments tubes, by the increasing unsightliness characteristic of many ointment tubes during use. Paper labels may be used, labeling may be silk screened onto plastic surface. Expiration data and code lot number may be stamped on as a part of the tube crimping procedure.

2. Labelling of Ophthalmic Preparation:

The European pharmacopoeia and BP specify the following requirement for labeling of ophthalmic preparation.

A) Eye Drops:

The label should state the name and concentration of any antimicrobial preservative or other substance added to the preparation.

B) Eye Ointments:

The label should state the name and concentration of any antimicrobial preservative or other auxiliary substance added to the preparation.

C) Eye Lotions:

The label should state the name and concentration of any antimicrobial preservative added to the preparation for single use container the label should state that the period after opening the container after which the content should not be used.

3. Labeling of Internal Powders:

Powders are usually mixed with water or other suitable liquid. Powder for babies or young children can be placed directly in mouth on the back of tongue, followed by a drink to wash out the powder. Bulk powder should be shaken and measured carefully before dissolving in little water and taking.

2. Machinery for Packaging

The machinery is an important technique 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

Features:

- It completes the functions such as vibrating material feeding, broken piece filtering, counting, lengthways and transverse, indentation, cutting waste material, marking batch number etc automatically.
- Vacuum shrink wrapping can prevent bacteria form & tear during transportation.
- The cutting speed and trip distance could be adjusted at random.
- With accurate feeding, tight sealing, full purpose, stable performance, easy operation.
- With this packing, the product grade will be enhanced, and product durability is extended. It is ideal equipment for pharmaceutical industry.

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.

Features:

Continuous motion rotary sealing is ideal for high blister output combined with rapid tool free change over. Intermittent motion platen sealing assures reliable production at medium output speeds & is particularly suitable for cold form aluminium.

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



Figure4: Ampoule filling machine

Specifications:

Applied for 1-20ml ampoule for washing, sterilizing, and filling

Used for 1-20ml ampoule, and 1-15ml vial filling.

Description:

These high precision machines completely encase the product in the inert glass & don not have a rubber stoper 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).

Features:

1. It requires minimal maintenance and is very easy to clean.
2. Mechanical gripper holds the ampoule around the washing machine, applicable to 1-20ml ampoule.
3. During washing process, ampoules do not need to be stopped. Both the water injector and air nozzle follow the moving ampoules, which can ensure an excellent quality of ampoule washing and super water-saving effect.
4. Both circulating water pipes and fine washing water pipes are assembled individually, which can prevents from extra contaminations

5. Buffering block is added in front of the spiral screw to prevent ampoule from being broken and protect the spiral screw
6. A cellular belt is adopted for ampoule out-feeding section, which allows for more stable and reliable transferring of ampoules in the process.
7. Heated air is circulated on the ampoule while sterilizing, which ensures excellent uniform temperature distribution and energy economy.
8. HEPA filter protection function is adopted to ensure high secure operation.
9. Round even-pace wheel instead of section block is adapted at ampoule in-feed station to reduce ampoule breaking rate significantly.
10. For filling and sealing machine, a locking device for its filling nozzle rest and sealing gripper rest is adopted.
11. For filling and sealing machine, the ceramic pump, SS pump, creeping pump is optional
12. For filling and sealing machine, the servo system is optional for driving filling pump.

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. Production speed can be adjusted by inverter.
7. Through PLC programmable and touch screen to operate equipment.
8. Comply with GMP requirements.
9. Supply GMP verification documents and assist to pass GMP validation.

6. Automatic Shrink Wrapping Machine

Description:

Shrink wrap machine make use of plastic to effectively seal a container or product by tightly surrounding it. Vacuum shrink wrapping can prevent bacteria from entering the product and also protect them from wear & tear during transportation.

- a. Features of Automatic Shrink Wrapping Machines:
- b. Adjustable belt speed by inverter
- c. Electronic counter-cycles
- d. Automatic control of the switch-on functions
- e. 4 product-reading photocells
- f. Visible and acoustic emergency signal
- g. 8 languages display
- h. Integrated and movable roll support
- i. Receiver for compressed air
- j. In-feed and out-feed electronic door to interface any additional feed belt

- k. Machine placed on adjustable feet and wheels
- l. New micro-puncher kit with adjustable tensioning film
- m. Possibility of packing single or multiple packages.

There are various types of shrink wrap machines used according to the product or material being wrapped.

- Heat guns are used to wrap blister packs.
- Vacuum sealers are used to shrink wrap pharmaceutical, nutraceutical & medicines.

Applications of Automatic Shrink Wrapping Machines:

Pesticides Bottle, Pharmaceutical Bottle, Textile, Cosmetic Items Like Talcum Powder Bottle, Books & Stationery Like Playing Cards, Mineral water, Food Products Like pickle bottle, Soap & shampoo Bottle, Gift Items, Welding rods, etc.

7. 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 / Sticking Machine



Figure 7: Automatic labeling machine

Discription:

- 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.
- Products of different diameter like small size of vials, bottles upto containers can be accommodated in the same machine. Speed is depend on the length of label.
- Labeling speed is automatically synchronized with conveyor speed to ensure quality.

There are different types of Automatic labeling machines as follows

1. Fully Automatic Single Side Sticker Labeling Machine
2. Fully Automatic Double Side (front & back) Sticker Labeling Machines
3. Fully Automatic High Speed Sticker Labeling Machine

Automatically labels on round containers of glass and plastic with wrap round labels and also flag type in the vertical position by using cold glue. This machine is rugged, versatile and enhances operational efficiency.

Advantages: Hundreds of units installed in the pharmaceuticals, cosmetics, food plants and also liquor industries are boosting profiles by giving the products a distinctive look.

Printing Process:

The most widely used method of printing labels is letterpress. It permits good colour control with clear, sharp detail. A variation of this, in which the printing is not direct from plate to paper but is transferred from the plate to a rubber roller and then to a paper, is called letterset. The fastest growing technique is flexographic printing. Quality of this type of printing is not best but it requires the least expensive equipment. For this reason it is popular in the smaller shops and is used for printing pressure sensitive labels. Colour log down is excellent and particularly with fluorescent inks it gives better coverage than any other process. Practically time is nil, and results are very consistent. For limited use, screen printing is applicable to very short runs. A very heavy lay down of colour is possible. Computers are being used to print labels where a great variety of labels in small quantities are needed. An intelligent dot matrix printer is connected to central processing units with a cathode ray tube, screen and a keyboard. There are usually two disk drives that bring the information out of memory. One disk will contain the data for the label format is the size of type, borders, bar codes and general arrangement. Another disk will have the standard information for each product. If variable information, such as lot number or expiration has been verified on the screen, the command is given on the keyboard to print the required number of labels. The printer produces the labels at 600 lines per minute on fan folded paper that is perforated between labels.

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: The embossed character is clear impressed and widely used for all kinds of thickness of object printed.

Specification:

Object Thickness: 0.05-3.0m

Print speed: 0-300PCS/min adjustable step-less speed.

3. Conclusion

In recent decades pharmaceutical packaging technology is an important technique 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 compliances. 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.

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