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Labeling and Packaging

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Abstract: *Labels are displays of textual, printed, or visual content on a medication package's wrapping or immediate container. The phrase "labelling" refers to any labels and other written, printed, or visual content on or in any box or wrapper that contains a product, with the exception of any outside shipping containers. Packaging is the cost-effective way to present, safeguard, identify, inform, contain, make it convenient to use, maintain integrity, and stabilize a product. Packing types include primary, secondary, and tertiary. Materials Used in Packaging The type of medication or pharmaceutical product being packed determines the materials used in packaging. Glass container, rubber closure, and plastic materials evaluation test. Test for chemical resistance tests for hydrolytic resistance, argon resistance, leakage, transparency, self-seal ability, fragmentation, and light absorption. Labelling for various dosage forms, including manufacturing and dispensing labels. Patients may only find instructions on how to take their medications on the label of the prescription bottle. Federal law and state legislation in the United States provide the legal criteria for a prescription label. The container should maintain a product's identity, strength, quality, and purity as well as prevent contamination. It should be equivalent to the packaging used by manufacturers to package medicinal items. It should include safety features like a child-proof closure. The Food and Drug Administration (FDA) has not authorized pharmaceutical medicines acquired through overseas internet pharmacies, and they may not adhere to US labelling and packaging requirements.*

Keywords: Label, Packaging

I. INTRODUCTION

1.1 Labeling

- Labels are displays of textual, printed, or visual content on a medication package's wrapping or immediate container.
- The phrase "labelling" refers to any labels and other written, printed, or visual content on or in any box or wrapper that contains a product, with the exception of any outside shipping containers.
- All medicine labels in India must comply with the requirements set forth in the 1945 Drugs Act and Cosmetics Rules.

It includes information regarding:
Information about indications, outcomes, dose, frequency and length of administration, dangers, side effects, contraindications, precautions, and other pertinent details.

Function of Label

Ingredients, the product's intended use, child safety, and other information like thenumber and shelf life are all required for product identification.

Importance of Labeling

Users must pay close attention to the labels and packaging of all medications in order to use them safely.
All labels must be short and clear and provide all important information on how to use a product safely.

1.2 Packaging

- Packaging is the cost-effective way to present, safeguard, identify, inform, contain, make it convenient to use, maintain integrity, and stabilise a product.
- The science, art, and technology of packaging involves confining or safeguarding goods for distribution, storage, sale, and usage. It also relates to the design, review, and manufacturing processes for packages.

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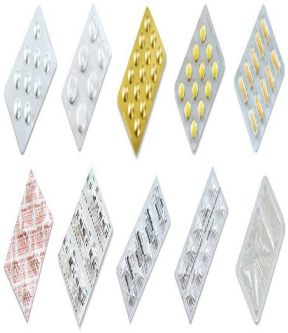
1.3 Types of Packaging

- **Primary Packaging:** It is the substance that first envelops and retains the product. Typically, this is the smallest distribution or usage unit. Ex: bottles, blister packs, and aerosol spray cans.




- **Secondary Packaging:** The primary packaging's exterior may be utilized to bundle primary packages together. Ex-Cartons and boxes


- **Tertiary Packaging:** It is employed in bulk transportation and handling. Barrel, container, edge protector, etc

1.4 Packaging Materials

- The type of medication or pharmaceutical product being packaged determines the choice of packaging materials.
- For dry powder and liquid-based goods, pharmaceutical glass vials, bottles, and ampoules are used.
- Pharmaceutical pills, capsules, powders, and granulates are packaged in plastic.
- Aluminum foil is used to package pills and capsules in blisters.
- blister packs, polybags, and pharmaceutical sachets are examples of packaging made of plastic and polymers.
- plastic caps and closures that resist tampering.
- For secondary and tertiary packaging of pharmaceutical items, carton boxes, shipping crates, and injection trays are further utilised.

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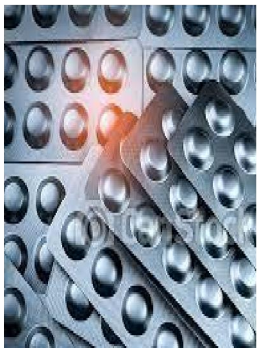
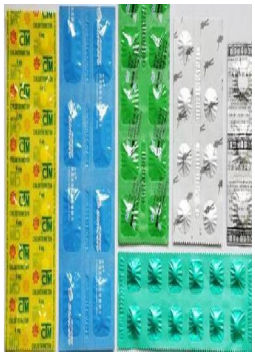


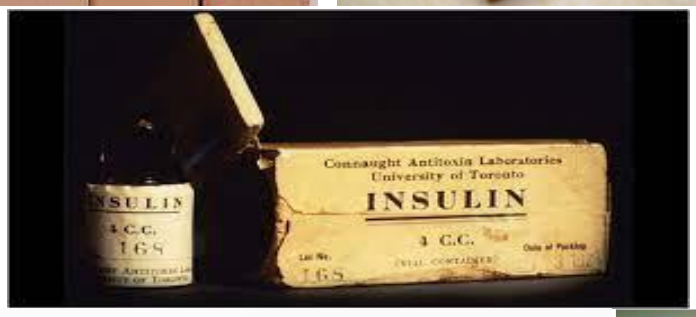




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1.5 Evaluation Tests for Packaging Materials

- Evaluation is done to look into any potential physicochemical interactions between the product and the packaging. The ideal container would have the longest possible shelf life and be fully inert to the substance.
- To produce a safe, pure, stable, and effective product, evaluation is created to recognize, describe, and track these interactions.
- A quality control plan may assist assure compatibility and safety while also helping to establish the initial qualification of the container closing system through a variety of tests.

GLASS

Glass is one of the materials that is most frequently used to make baby products, thus extra care must be given while using glass.

Composition of Glass	Types of Glass
Glass is composed of sand, soda ash, lime stone and cull.et	Type 1: -Neutral or Borosilicate glass. Type 2: -Treated Soda-lime glass. Type 3: -Regular Soda-lime glass. Type 4: -General purpose Soda-lime glass.

Evaluation Tests of Glass Containers

Chemical Resistance of Glass Containers

Powdered Glass Test | Water Attack Test

Hydrolytic Resistance Test

Powdered Glass Test:

Preparation of glass specimen:

It is done to calculate the quantity of alkali that is typically leached from powdered glass at high temperatures. The leaching of alkali is increased when the glass is powdered, and it may be measured using 0.02N sulfuric acid using methyl red as an indicator.

Getting ready the glass specimen:

A stream of clean air is used to dry a few containers after they have been fully cleaned with purified water. Put the containers in a mortar and pestle and grind them into a fine powder

The specimen is cleaned by placing 10g of the aforementioned sample into a 250 ml conical flask and cleaning it with 30 ml of acetone. Repeat the cleaning process, decant the acetone, and let it dry before using it within 48 hours.

Procedure:

Transfer 10.0g of prepared specimen in250ml conical flask digested previously with high purity water in bath at 90^0c.

Add to conical flask containing 50ml of high purity water

Cap all the flask

Autoclave (continue heating for 10min)

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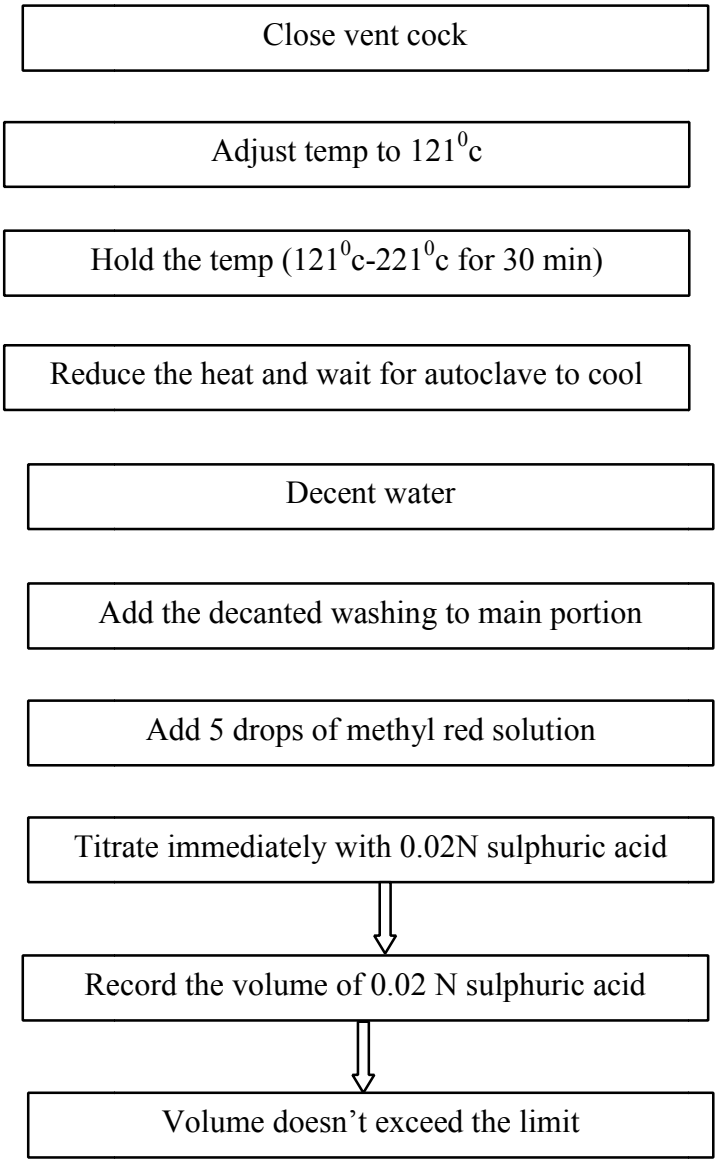

Testes	Containers	ml of 0.02 N H2SO4
Powder glass test	Type 1 Type 3 Type NP	1 8.5 15

Water Attack Test:

This only applies to treated soda lime glass containers with regulated humidity levels, which neutralize the surface alkali and increase the chemical resistance of the glass. Whether or if the alkali leached off the container's surface is the key question.

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Procedure:

Rinse 3 or more containers with high purity water

Fill each container to 90% of its overflow capacity

Cap all the flasks, autoclave for 60 min

Empty the containers and cool contents in 250ml flask to a volume 100ml

Add five drops of methyl red solution

Titrate with 0.02N Sulphuric acid while warm

Record the volume consumed

Volume should not exceed limits

Testes	Containers	ml of 0.02 N H_2SO_4
Water attack test	Type 2(100 ml or less) Type 2(over 100ml)	0.7 0.2

Hydrolytic Resistance of Glass Containers:
This examination is conducted to determine the kind of glass.

Types of containers	Test to be done
Type 1 and type 2 glass containers to distinguish from type 3 glass containers.	Test 1(surface test)
Glass containers of type 1 and type 2, where it is important to ascertain whether the surface or the chemical composition is to blame for the high hydrolytic resistance.	Test 1 and 2

Test 1- Surface glass test.

Wash containers with carbon dioxide free water

Fill the containers with CO_2 free water(90%)

Close with aluminum foil

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Autoclave at 100°-120l°C for 20 min

Maintain at 120°C for 1 hr

At lower temp for 40 min

Remove containers and cool

Titrate it within 1hour

Titrate with 0.01 M HCL (end point colorless)

Repeat with same volume of CO_2 free water

Volume of test solution to be used:

Sr. no	Nominal capacity of container (ml)	No. of containers to be used	Volume of test solution to be used (ml)
1	Up to 3	At least 20	25.0
2	5 or less	At least	50.0
3	6 to 30	At least	50.0
4	More than 30	At least	100.0

Test 2:

Rinse container twice with water and with 4% volume solution of HF

Allow to stand for 10 min

Empty the container

Rinse 5 times with water

Carry out test similar test 1

Arsenic Test:

This e treatment test is for glass containers intended for aqueous parenteral.

Inner and outer surface are washed 5 times with freshly prepared distilled water

Prepare 50 ml using adequate number of least solution

Pipette out 10ml of test solution from combined content of ampoule into flask

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Add 10 ml of HNO3

Evaporate to dryness of water bath

Add the residue in an oven at 130 C for 30 min

Cool, add to hydrazine molybdate reagent to dissolve

Heat under reflux on water bath for 20min

Cool to room temperature

Determine the absorbance of resulting solution at maximum of about 840 nm using hydrazine molybdate reagent as a blank

Limit 0.1 ml of arsenic std

PLASTIC:

High molecular weight synthetic polymers make up plastic. One or more polymers are combined with certain additives to create plastic. Polyethylene, polypropylene, polyvinyl, and other polymers are often utilized. Two types of plastic are them

a) Thermoplastic type

b) Thermosetting type

Evaluation Tests of Plastic containers

Leakage Test:

10 water-filled containers with their appropriate lids are used.

For 24 hours, they are maintained inverted at room temperature.

If there are no indications of any container leakage, the test is said to have been successful.

plastic bottles kept upside-down

Collapsibility Test:

Clarity of aqueous extract: This test is relevant to containers whose contents are to be squeezed out for removal. At least 90% of a container's usual contents will be released when it collapses inwards during usage at the necessary flow rate and ambient temperature.

Unlabeled, unmarked, and unlaminated chunks are randomly chosen from a suitable container.

These pieces are divided into strips, none of which has a surface area greater than 20 cm2.

Strips are cleaned of foreign objects by shaking them for about 30 seconds with at least two different amounts of distilled water.

The cleaned with chromic acid and washed with distilled water flask is filled with the processed sample.

The flask is filled with 250 ml of distilled water, covered, and autoclaved at 121°C for 30 minutes.

The extract is chilled before inspection.

It ought to be turbid-free and colourless.

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Water Vapor Permeability:

5 containers are heated-sealed with aluminium foil, polyethylene laminate, or another acceptable seal after being filled with a minimal amount of water.

Each container is weighed and left unprotected for 14 days at a temperature between 20 and 25 °C with a relative humidity of 60 + 5%.

Containers are reweighed (each container's weight loss cannot exceed 0.2%)

Transparency Test:

Standard suspension preparation: -1 g of hydrazine sulphate in 100 ml of water; leave for 6 hours. Add 25ml of 10%w/v hexamine to 25ml of this solution, and let it stand for 24 hours.

Test solution preparation: - The sample is created by diluting the normal solution 16 times. Fill 5 containers to the point where cloudiness can be distinguished from water-filled containers. The range of absorbance at 640 nm is between 0.37 and 0.43.

CLOSURES

The tools used to open or shut containers are known as plastic closures.

A closure is the portion of a package that keeps the contents within and prevents outside material from getting inside.

It stops the product from degrading due to environmental factors like moisture, oxygen, or carbon dioxide.

Types of Closures	Material used for making of Closures
1. Threaded screw cap	1. Cork
2. lug cap	2. Glass
3. Crown cap	3. Plastic
4. Roll on closures	4. Metal
5. Pilfer proof closures	5.Rubber

Evaluation Tests for Closures

Fragmentation Test:

The closures that are designed to be penetrated by a hypodermic needle are subject to this test.

4 ml of water is added to 12 clean vials, and the lids are put on.

16 hours of standing permission

1 ml of water and 1 ml of air are added to the vial with the use of a hypodermic needle.

Four repeats of this procedure are performed, each time using a different needle.

A filter with 0.5-micron pore size is used to filter the water in the vial.

The maximum allowed number of closure pieces should be kept.

Limits: - Not more than 10 pieces in total (in case of butyl rubber) Not more than 15 pieces in total

Self Seal-Ability Test:

10 vials are filled with a small amount of water, and then the closures are put on them.

10 distinct locations on caps are punctured using hypodermic needles.

Under pressure, methylene blue solution at 0.1% w/v is submerged in vials.

Containers are submerged for thirty minutes.

There should be no residues of color solution in any of the rinsed vials.

Light absorption Test: -

It has to be finished four hours after preparing solution A. It is filtered using a 0.5-micron filter, and the absorbance ranges from 220 to 360 nm. There are no closures used in the blank, and the absorbance is NMT 2.0.

Labeling for different dosage forms:

Labels are displays of textual, printed, or visual content on a medication package's wrapping or immediate container.

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Types of labeling:

1) Manufacturer label
2) Dispensing label

Manufacturer Label

A label issued by the medicine's maker, packer, or distributor that includes drug information for use by doctors, pharmacists, or nurses.

Manufacturer label

Legal Requirements of a Manufacturer Lable

1. Generic and brand names for the medication
2. Strength and dosage form

It is the quantity of the active ingredient in each dosage.

The medication's dosage form, such as capsule, tablet, syrup, or suspension, should be noted on the label.

Strength

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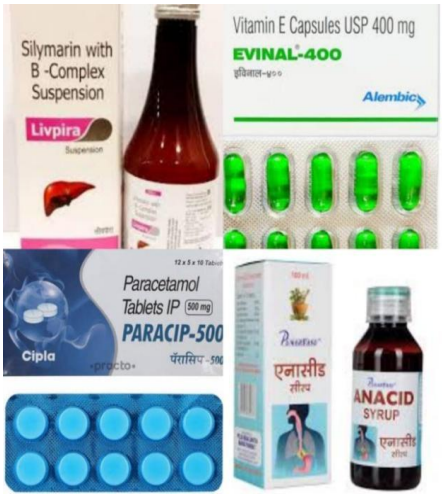
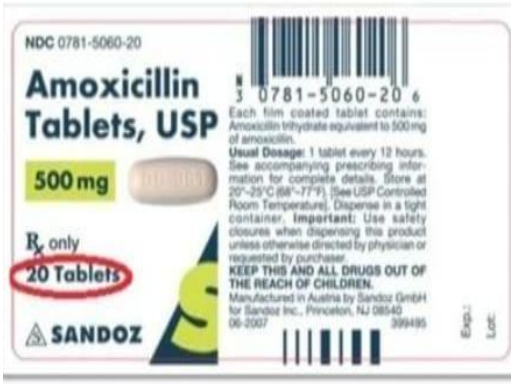
Dosage form



Quantity

Quantity/volume present per a packaging unit.

Quantity



Instructions for the use-Keep in the refrigerator, before using, give a good shake.

Precautions

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Precautions and Warnings

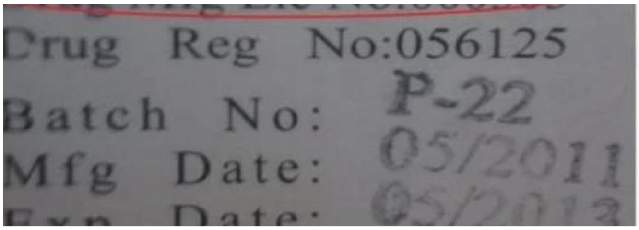
Headache and sleepiness potential, only for external usage

Warning

Registration Number

A number assigned to a certain medicine when it is registered by the registration board established by the federal government in accordance with certain laws.

Registration number

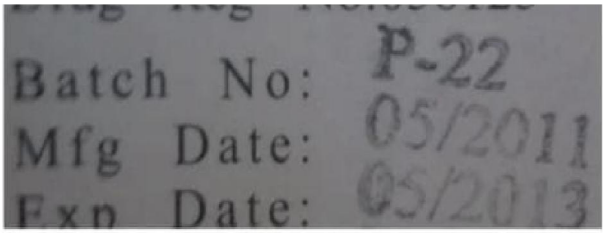


Batch Number

Based on the 1976 Drug Act.

"A designation written on a drug's label that identifies the batch and allows for the viewing and tracing of the batch's manufacturing history, including all manufacturer and control satages"

Batch number



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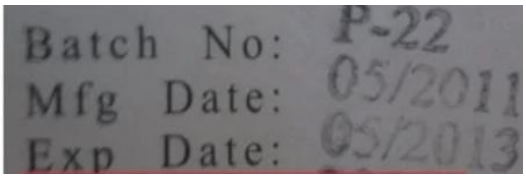
Manufacturing date & Expiry date.

According to drug act 1976 S_3.

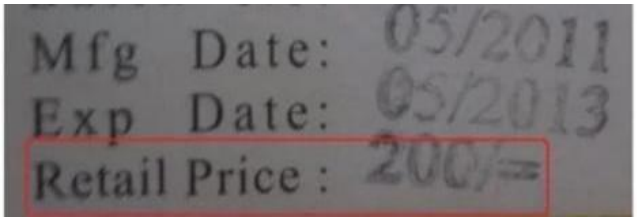
Manufacture date and Expire date



Price

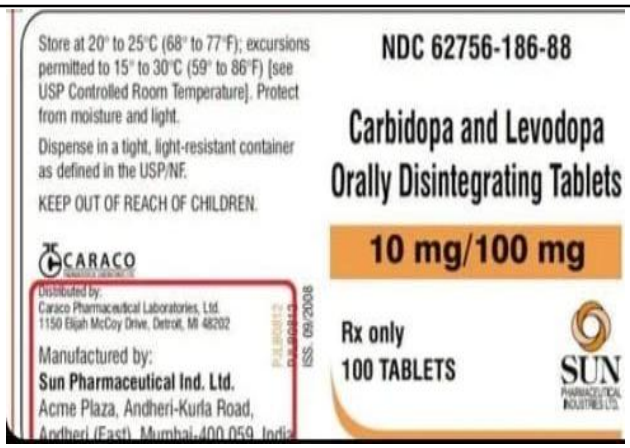
Retail price, MRP

Price



Name and Address of Pharmaceutical Industry.

Name and address of pharmaceutical industry.



Dispensing Label

A label that includes the patient's name, strength, batch number, and expiration date of the medication, as well as dose and usage directions, delivery date, storage instructions, and the name and address of the pharmacy.

Dispensing label

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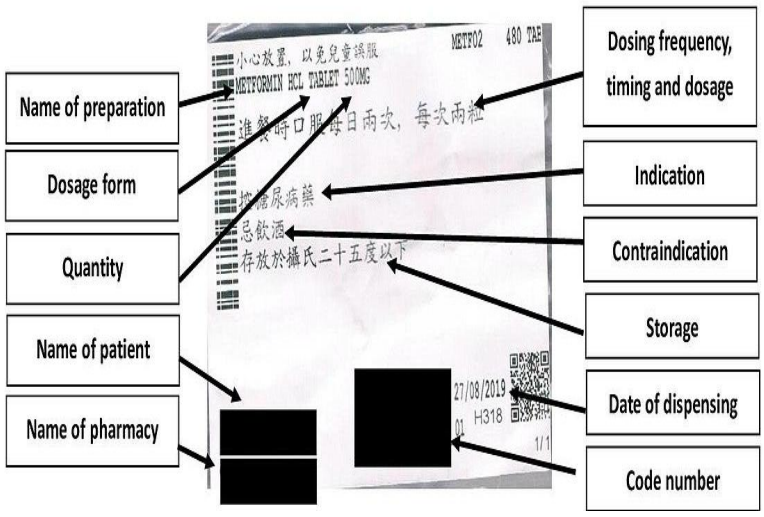

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