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PHARMACEUTICAL QUALITY ASSURANCE

UNIT 3

TOPIC :

- **Quality Control :** Quality control test for containers, rubber closures and secondary packing materials



Quality Control Tests of Packaging Materials, Containers And Closures

Quality Control (QC) Tests are procedures performed to ensure that packaging materials, containers, and closures meet specified standards of quality, safety, performance, and compatibility.

These tests ensure that packaging materials:

- Protect the pharmaceutical product.
- Prevent contamination.
- Maintain stability of the drug.
- Ensure safe storage and transportation.
- Comply with pharmacopoeial standards.

Packaging Materials

- Packaging materials are materials used to enclose, protect, preserve, identify, and transport pharmaceutical products.

Functions of Packaging

- Protection from moisture.
- Protection from light.
- Protection from contamination.
- Easy handling and transportation.
- Product identification.
- Patient information and labeling.

Types of Packaging Materials

1. Primary Packaging

→ Primary packaging is in direct contact with the pharmaceutical product.

Functions

- Provides primary protection.
- Maintains product stability.
- Prevents contamination.

Examples

- Blister packs for tablets.
- Bottles for syrups.
- Ampoules and vials for injections.

2. Secondary Packaging

→ Secondary packaging surrounds the primary package.

Functions

- Additional protection.
- Product identification.
- Information display.
- Marketing and branding.

Examples

- Cartons.
- Paper boxes.
- Package inserts and leaflets.

3. Tertiary Packaging

→ Used for bulk handling and transportation.

Functions

- Protects products during shipping.
- Facilitates storage and distribution.

Examples

- Corrugated boxes.
- Shipping containers.
- Pallets.

Containers

→ A container is a receptacle that holds pharmaceutical products and protects them from external factors such as moisture, light, air, and contamination.

Types of Containers

1. Glass Containers
2. Plastic Containers
3. Metal Containers

1. Glass Containers

➤ Glass is the most commonly used pharmaceutical packaging material because it is chemically inert, impermeable, transparent, and easy to sterilize.

Properties of Glass

- Chemically inert.
- Non-reactive with drugs.
- Impermeable to moisture and gases.
- Provides excellent product protection.
- Transparent or amber colored.
- Can be sterilized easily.

Types of Pharmaceutical Glass

Type I Glass (Borosilicate Glass)

Composition

- Silica
- Boron oxide

Characteristics

- Highest chemical resistance.
- High thermal resistance.
- Does not release alkali.

Uses

- Injectable products.
- Parenteral preparations.
- Sensitive pharmaceutical products.

Type II Glass (Treated Soda-Lime Glass)

Characteristics

- Surface treated with sulfur dioxide.
- Good chemical resistance.

Uses

- Intravenous fluids.
- Acidic and neutral aqueous preparations.

Type III Glass (Soda-Lime Glass)

Characteristics

- Moderate chemical resistance.
- Releases small amounts of alkali.

Uses

- Syrups.
- Tablets.
- Oral preparations.

Type IV Glass (General Purpose Glass)

Characteristics

- Lowest chemical resistance.

Uses

- External preparations.
- Non-parenteral products.

Quality Control Tests For Glass Containers

1. Chemical Resistance Test

→ Determines the resistance of glass to chemical attack and alkali release.

Types

- Powdered Glass Test
- Water Attack Test

Powdered Glass Test

Principle

→ Measures alkali released from powdered glass.

Procedure

1. Wash and dry glass containers.
2. Crush into fine powder.
3. Pass through sieve No. 20 and 50.
4. Take 10 g powder.
5. Wash with acetone.
6. Add 50 mL purified water.
7. Autoclave at 121°C for 30 minutes.
8. Cool and decant liquid.
9. Titrate with 0.02 N H_2SO_4 .

Limits

Glass Type	Maximum Volume of 0.02N H_2SO_4
Type I	1.0 mL
Type II	3.5 mL
Type III	15.0 mL

Water Attack Test

Principle

→ Measures chemical resistance of intact glass containers.

Procedure

1. Fill container with distilled water.
2. Fill up to 90% capacity.
3. Autoclave at 121°C for 30 minutes.
4. Cool the sample.
5. Separate liquid.
6. Titrate with 0.02 N H_2SO_4 .

Acceptance

Volume consumed must be within pharmacopoeial limits.

2. Plastic Containers

- Plastic containers are packaging systems made from polymeric materials such as polyethylene, polypropylene, and PVC.

Advantages

- Lightweight.
- Unbreakable.
- Economical.
- Easy handling.

Quality Control Tests for Plastic Containers

1. Leakage Test

Procedure

1. Fill with colored water.
2. Close tightly.
3. Place under vacuum.
4. Observe for leakage or bubbles.

Result

No leakage = Pass.

2. Collapsibility Test

Purpose

Ensures easy dispensing of contents.

Procedure

1. Fill container.
2. Apply pressure.
3. Container should collapse uniformly.
4. Release approximately 90% contents.

Result

Uniform collapse = Pass.

3. Metal Containers

→ Metal containers are made from aluminum or tin-plated steel and are commonly used for ointments, creams, and aerosols.

Quality Control Test For Metal Containers

Metal Particle Test

Purpose

→ Detects metal particles released from collapsible tubes.

Procedure

1. Clean 50 tubes.
2. Fill with molten ointment base.
3. Seal and cool.
4. Remove ointment.
5. Filter molten ointment.
6. Observe filter paper under magnification.
7. Count metal particles.

Scoring System

Particle Size	Score
≥ 1 mm	50
0.5–1 mm	10
0.2–0.5 mm	2
< 0.2 mm	1

Limits

- < 100 = Pass
 - 150 = Fail
- 100–150 = Retest Required

Closures

→ Closures are devices used to seal pharmaceutical containers and protect products from contamination, leakage, and moisture.

Types

- Rubber Closures
- Plastic Closures
- Metal Closures

1. Rubber Closures

➤ Rubber closures are flexible sealing devices made from natural or synthetic rubber.

Uses

- Injection vials
- Bottles
- Sterile containers

Quality Control Tests for Rubber Closures

1. Residue on Evaporation Test

Purpose

→ Measures non-volatile impurities.

Procedure

1. Wash closures.
2. Autoclave at 119–123°C.
3. Prepare extract solution.
4. Evaporate 50 mL sample at 105°C.
5. Measure residue.

Limit

- Not more than 4 mg.

2. pH of Aqueous Extract

Purpose

Checks acidity or alkalinity.

Procedure

1. Prepare extract solution.
2. Add bromothymol blue indicator.
3. Titrate with NaOH.

Limit

- NaOH consumption should not exceed 0.3 mL.

3. Sterility Test

Purpose

Ensures closure is free from microorganisms.

Procedure

1. Sterilize closures.
2. Place in sterile culture media.
3. Incubate.
4. Observe microbial growth.

Result

No turbidity = Pass.

Secondary Packaging

→ Secondary packaging is the outer package that contains one or more primary packages.

Functions

- Additional protection.
- Product identification.
- Labeling and branding.
- Storage and transportation support.

Materials Used in Secondary Packaging

- Paper
- Paperboard
- Cartons
- Corrugated Fiberboard

Quality Control Tests for Secondary Packaging

1. Grammage Test

→ Measures weight per unit area (GSM).

Importance

- Indicates paper strength.
- Higher GSM = Stronger material.

2. Thickness Test

→ Measures thickness of paper or board.

Importance

- Determines stiffness and strength.

3. Moisture Content Test

→ Measures water content in paper.

Importance

- High moisture weakens paper.
- Low moisture causes brittleness.

4. Folding Endurance Test

→ Measures resistance to repeated folding.

Importance

- Indicates flexibility and durability.

5. Bursting Strength Test

→ Measures resistance to bursting pressure.

Importance

- Indicates paper strength.