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INDUSTRIAL PHARMACY - I

UNIT 5

TOPIC :

- **Packaging Materials Science :** Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

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Materials Used for Pharmaceutical Packaging

Pharmaceutical packaging plays a critical role in protecting drug products from physical, chemical, and microbial degradation, ensuring safety, stability, efficacy, and patient compliance.

- Primary packaging: Direct contact with the product (e.g., bottles, ampoules).
- Secondary packaging: External protection and labeling (e.g., cartons, boxes).
- Tertiary packaging: Bulk transport (e.g., shipping containers, pallets).

The selection of packaging material depends on:

- Compatibility with the drug.
- Protection from moisture, light, oxygen, and microbes.
- Mechanical strength, cost, and regulatory compliance.

Glass

Types:

1. Type I (Borosilicate Glass): Chemically resistant, high thermal resistance.
2. Type II (Treated Soda-lime Glass): Chemically treated to reduce alkalinity.
3. Type III (Soda-lime Glass): Less chemically resistant, for less sensitive drugs.

Properties:

- Transparent or colored.
- Chemically inert.
- Impermeable to gases and moisture.
- Resistant to microbial contamination.

Advantages:

- Excellent chemical compatibility.
- High barrier to moisture and oxygen.
- Suitable for sterilization (autoclaving).

Disadvantages:

- Brittle, can break easily.
- Heavy compared to plastics.

Applications:

- Injectable vials, ampoules, oral liquid bottles, ophthalmic bottles, lyophilized products.

Plastics / Polymers

Common Polymers:

- Polyethylene (PE): Flexible, moisture-resistant; bottles, closures.
- Polypropylene (PP): Heat-resistant, autoclavable; syringes, caps.
- Polyvinyl Chloride (PVC): Flexible, clear; IV bags, blister packs.
- Polyethylene Terephthalate (PET): Strong, transparent; bottles for oral liquids.
- Polystyrene (PS): Rigid; jars, caps.

Properties:

- Lightweight, shatterproof.
- Chemically compatible with most drugs.
- Can be transparent or colored.

Advantages:

- Low cost, easy molding, variety of shapes.
- Shatterproof, suitable for transport.

Disadvantages:

- Permeable to gases in some cases.
- Can interact with lipophilic drugs.

Applications:

- Bottles, tubes, syringes, IV bags, blister packs, topical containers.

Metals

Common Metals: Aluminum, tinplate, stainless steel.

Properties:

- Durable, high mechanical strength.
- Impermeable to light, moisture, and oxygen.
- Resistant to microbial contamination.

Advantages:

- Good barrier properties.
- Suitable for pressurized products (e.g., aerosols).

Disadvantages:

- Heavy.
- May react with acidic or basic drugs if not lined.

Applications:

- Aluminum: Tablets, capsules, ointments, aerosols.
- Tinplate: Powder and ointment cans.
- Stainless steel: Bulk storage containers, reactors, and industrial packaging.

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Paper and Paperboard

Properties:

- Lightweight, printable, biodegradable.
- Permeable to moisture unless laminated.

Advantages:

- Easy for printing instructions, branding, and labels.
- Economical and recyclable.

Disadvantages:

- Poor barrier against moisture and gases.

Applications:

- Secondary packaging, cartons, blister pack backing, inserts, labels.

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Rubber / Elastomers

Types:

- Natural rubber, synthetic rubber (butyl, silicone, neoprene).

Properties:

- Flexible, elastic, and chemically resistant.
- Compatible with sterilization processes (autoclave, gamma).

Advantages:

- Provides airtight sealing.
- Resistant to microbial contamination.

Disadvantages:

- Can absorb certain drug molecules (especially lipophilic drugs).
- May react with some oxidizing agents.

Applications:

- Stoppers, vial seals, dropper tips, inhaler seals, syringe plungers.

Composite / Laminated Materials

Composition:

- Combination of plastic, aluminum, and paper.

Properties:

- Provides barrier to moisture, light, oxygen.
- Flexible and lightweight.

Advantages:

- Excellent protection for sensitive drugs.
- Can be heat-sealed or printed.

Disadvantages:

- Higher cost than single-material packaging.

Applications:

- Blister packs for tablets/capsules, sachets, tubes for ointments and creams.

Selection Criteria for Pharmaceutical Packaging

1. Chemical compatibility – Must not react with drug.
2. Barrier properties – Protect against moisture, light, and oxygen.
3. Mechanical strength – Prevent breakage during handling.
4. User-friendliness – Easy to open, dispense, and tamper-evident.
5. Regulatory compliance – Meet FDA, ICH, IP, USP standards.
6. Cost-effectiveness – Economical for large-scale manufacturing.

Factors Influencing Choice of Containers

1. Nature of the product
    - Liquid, powder, ointment, aerosol, tablet, or capsule.
    - Example: Injectables require Type I glass or plastic compatible with sterilization.
2. Chemical stability of the drug
    - Protect from moisture, oxygen, light, or chemical interactions.
3. Physical properties
    - Viscosity, corrosiveness, reactivity, or sensitivity to pressure.
4. Mode of administration
    - Parenterals require sterile, air-tight containers.
    - Topicals may use tubes or jars.
5. Storage and transportation conditions
    - Temperature, humidity, mechanical stress, and light exposure.
6. Regulatory and official requirements
    - Must comply with Pharmacopoeial, FDA, and CDSCO standards.
7. Patient convenience
    - Ease of opening, handling, and dosing.

Legal and Official Requirements for Containers

- Must comply with Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), or USP.
- Parenteral containers:
    - Sterile, pyrogen-free, chemically inert.
    - Example: Type I glass or suitable plastics.
- Oral liquids:
    - Glass or plastic bottles that do not interact with the drug.
- Labelling Requirements:
    - Name of product, strength, batch number, manufacturing and expiry date, storage instructions, and manufacturer details.
- Containers must maintain drug identity, purity, strength, and quality throughout shelf life.

Stability Aspects of Packaging Materials

1. Chemical Compatibility
    - Drug should not react with container or closure.
    - Example: Ascorbic acid is sensitive to oxygen-permeable plastics.
2. Moisture Barrier
    - Protect hygroscopic drugs (e.g., aspirin, powders) from moisture.
3. Light Protection
    - Photosensitive drugs require amber glass or opaque packaging.
4. Thermal Stability
    - Must withstand storage temperature and sterilization conditions.
5. Mechanical Stability
    - Containers should resist breakage during handling and transport.
6. Interaction with Closures
    - Rubber stoppers and plastic caps must not leach chemicals or adsorb drug.

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Quality Control (QC) Tests for Packaging Materials

Importance of QC for Packaging Materials

- Packaging materials play a critical role in drug stability, safety, and efficacy.
- QC ensures:
  1. Integrity – no leaks, cracks, or defects.
  2. Compatibility – no chemical interaction with the drug.
  3. Durability – withstand handling, transport, and storage.
  4. Barrier properties – prevent moisture, oxygen, or light ingress.
  5. Regulatory compliance – meets pharmacopoeial and legal standards.

Physical Tests

Test	Purpose / Description	Method / Example
Leakage Test	Ensures container is hermetically sealed and leak-proof.	Immerse filled container in water under pressure; observe for bubbles.
Tensile / Mechanical Strength Test	Checks durability, flexibility, and resistance to breakage.	Apply force to bottles, tubes, closures; measure elongation or fracture point.
Dimensional / Thickness Test	Ensures uniform wall thickness and dimensions.	Measure glass wall thickness, tube diameter, or closure dimensions with calipers.
Impact / Drop Test	Simulates handling stress to check container strength.	Drop filled container from standard height; observe for breakage or leakage.
Closure Function Test	Evaluates tightness and sealing efficiency.	Torque testing of screw caps, compression test for rubber stoppers.
Transparency / Clarity Test	Checks visual clarity of glass or plastic for	Visual inspection against standard background or light.

	inspection.	

Chemical Tests

Test	Purpose / Description	Method / Example
Extractable / Leachable Test	Ensures no harmful substances leach into drug.	Immerse packaging in suitable solvent; analyze via HPLC, GC, or spectrophotometry.
pH Compatibility Test	Checks reaction of material with acidic/basic drugs.	Store drug in container; monitor pH over time.
Solvent Resistance	Ensures container/closure does not degrade in presence of solvents.	Expose packaging to solvents; check for swelling, cracking, or dissolution.

Barrier Property Tests

Test	Purpose / Description	Method / Example
Moisture Vapor Transmission Rate (MVTR)	Measures container's ability to prevent moisture ingress.	Gravimetric or calcium chloride method for films/plastics.
Oxygen Transmission Rate (OTR)	Evaluates oxygen permeability to protect oxidizable drugs.	Use manometric or coulometric methods for plastic or laminated materials.
Light Transmission Test	Ensures protection of photosensitive drugs.	Measure % transmission in UV-visible range using spectrophotometer.

Sterility and Microbiological Tests

- Applicable for parenteral containers, ophthalmic bottles, and closures.
- Tests include:
  - Sterility test (as per USP/IP)
  - Endotoxin / pyrogen test (for parenterals)

- Microbial limit test (for non-sterile packaging)

Compatibility / Stability Testing

- Purpose: Evaluate interaction between drug and packaging over storage.
- Parameters monitored:
  1. Drug assay and content uniformity
  2. Physical changes – color, clarity, precipitation
  3. Propellant loss (for aerosols)
  4. Seal integrity and valve function (for parenterals/aerosols)
- Conditions: Accelerated and long-term stability as per ICH guidelines.

Special Tests for Specific Packaging

Packaging Type	QC Test	Purpose
Glass vials / ampoules	Hydrolytic resistance (Type I, II, III)	Ensure chemical resistance to drug solutions
Plastic bottles	Stress cracking / impact	Prevent breakage during storage/transport
Blister packs / laminated films	Adhesion and peel strength	Ensure tablet/capsule remains sealed
Aerosol cans	Valve leakage and spray uniformity	Maintain dose accuracy and propellant integrity
Tubes (metal/plastic)	Crimping/sealing integrity	Prevent leakage or contamination