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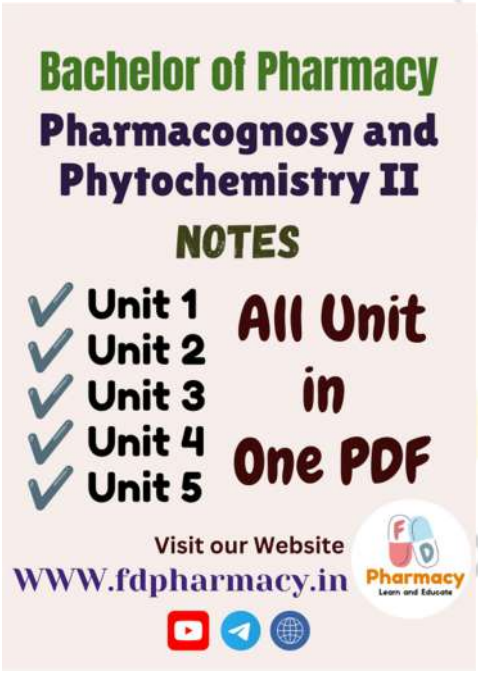
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INDUSTRIAL PHARMACY - I

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.

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.

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.

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.

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 inspection.	Visual inspection against standard background or light.

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