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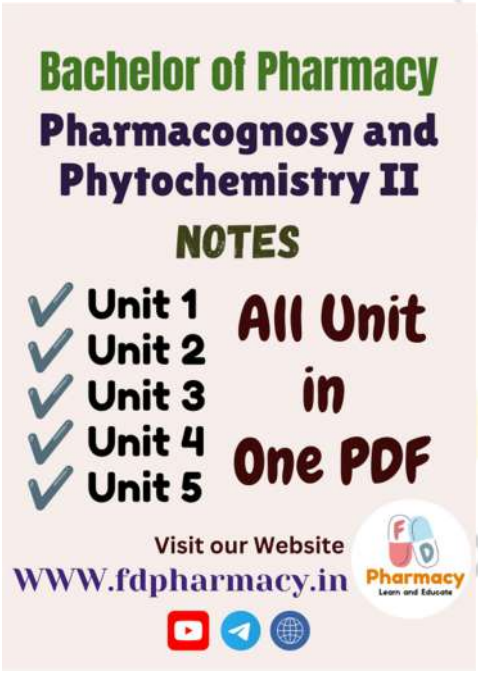
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INDUSTRIAL PHARMACY - I

UNIT 5

TOPIC :

- **Pharmaceutical Aerosols :** Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Pharmaceutical Aerosols

- Pharmaceutical aerosols are pressurized dosage forms that release medicinal substances in the form of fine particles, mist, or droplets when actuated.
- They are intended for topical, inhalation, or systemic use.
- Common examples: Inhalers, nasal sprays, topical sprays, metered-dose inhalers (MDIs).

Components of Pharmaceutical Aerosols

A pharmaceutical aerosol has three main components:

1. Active Ingredient (Drug)
    - Can be liquid, suspension, or powder.
    - Examples: Salbutamol, Beclomethasone, Diclofenac.
2. Propellants
    - Provide pressure to expel the product.
    - Types:
        - Gaseous Propellants: Compressed air, nitrogen.
        - Liquefied Propellants: Hydrocarbons (Propane, Butane, Isobutane), Hydrofluoroalkanes (HFA-134a, HFA-227).
    - Selection Criteria: Chemical inertness, solubility, non-toxicity, vapor pressure, compatibility with formulation.
3. Container
    - Must withstand high pressure, be chemically inert, and allow dispensing via a valve.
    - Types:
        - Aluminum cans – light, corrosion-resistant.
        - Tin-plated steel cans – economical, strong.
        - Glass containers – used for specialty products with protective coating.
4. Valve System
    - Controls dose and spray pattern.
    - Components: Valve body, stem, gasket, spring.
    - Types:
        - Metered-dose valve – delivers fixed amount per actuation.
        - Continuous spray valve – delivers spray continuously.

Types of Aerosol Systems

1. Metered Dose Aerosols (MDAs / MDIs)
    - Delivers a precise quantity per actuation.
    - Used for inhalation therapy.
2. Topical Aerosols
    - Used for skin or mucous membranes.
    - Examples: Antiseptics, analgesic sprays.
3. Nasal Aerosols
    - For local or systemic delivery via nasal cavity.
    - Example: Oxymetazoline, Fluticasone nasal sprays.
4. Powder Aerosols
    - Deliver solid particles.
    - Requires specialized dry powder inhaler system.

Composition of Aerosols

Component	Function	Typical Examples / Range
Active drug / agent	Therapeutic or cosmetic effect	Salbutamol, Budesonide, Deodorant
Propellant	Provide pressure and aerosolization	Hydrofluoroalkanes (HFA-134a, HFA-227), CO_2, Nitrous oxide
Solvent / Vehicle	Dissolve drug or aid dispersion	Ethanol, Water, Oleic acid
Surfactants / Stabilizers	Prevent aggregation, enhance stability	Polysorbates, Oleic acid
Co-solvents / Humectants	Improve solubility of drug	Ethanol, Glycerin
Fragrance / Coloring agents	Cosmetic appeal (optional)	Perfume oils, approved dyes

Methods of Aerosol Manufacture

A. Cold Filling Method

1. Product is prepared at room temperature.
2. Propellant (liquefied gas) is added at low temperature into the aerosol container.
3. Common for HFA or hydrocarbon propellants that are liquefied at low temperature.
4. Advantages: Simpler process; minimizes degradation of heat-sensitive drugs.

B. Pressure Filling Method

1. Propellant is added under high pressure using specialized equipment.
2. Commonly used for compressed gas propellants (CO_2, N_2).
3. Product can be room temperature solution or suspension.
4. Requires pressure-rated filling machines.

C. Batch Filling / Combination Method

- Combination of cold filling and pressure filling for complex formulations like emulsions or foams.
- Ensures homogeneous dispersion of propellant in product.

General Manufacturing Steps

Step 1: Preparation of Formulation

- Prepare solution, suspension, emulsion, or gel of the active drug.
- Add stabilizers, surfactants, and co-solvents for uniformity.

Step 2: Filling into Containers

- Fill pre-sterilized aerosol cans with formulation under hygienic conditions.

Step 3: Charging with Propellant

- Introduce propellant under controlled temperature and pressure.
- Cold filling for liquefied gases; pressure filling for compressed gases.

Step 4: Sealing

- Seal cans with valve and actuator assembly.
- Ensure tight closure to maintain pressure.

Step 5: Homogenization

- Shake cans to ensure uniform dispersion of propellant in the formulation.

Step 6: Labelling and Packaging

- Label with active ingredient, propellant, instructions, batch number, expiry date.
- Package in cartons for protection during transport and storage.

Quality Control (QC) Tests

A. Physical Evaluation

1. Appearance / Visual Inspection
    - Color, clarity, homogeneity, and presence of particulate matter.
    - Suspensions or emulsions should be uniform with no phase separation.
2. Odor
    - Acceptable fragrance for cosmetic or patient compliance.
3. pH Measurement
    - Ensures compatibility with skin, eyes, or mucosa.
    - Typical range: 5–7 for topical; 6–8 for inhalation aerosols.
4. Viscosity / Rheology
    - Ensures proper flow, foam formation, and spray pattern.
5. Density / Weight per Unit Volume
    - Confirms uniformity of content and dose accuracy.

B. Mechanical Evaluation

1. Propellant Content / Pressure
    - Determines adequate pressurization and spray formation.
    - Checked using gravimetric or manometric methods.
2. Valve and Actuator Function
    - Ensures leak-free operation and consistent delivery.
3. Leak Test / Container Integrity
    - Confirms pressurized container is intact; prevents loss of product or propellant.

C. Performance Evaluation

1. Spray Pattern / Plume Geometry
    - Evaluates uniform dispersion, droplet size, and coverage area.
2. Particle / Droplet Size Distribution
    - Especially important for inhalation aerosols (1–5 µm optimal).
3. Foam Quality (if applicable)
    - Volume, persistence, and stability of foam.
4. Content Uniformity / Assay
    - Quantitative measurement of drug per actuation using HPLC, UV, or titration.
5. Spray Rate / Metered Dose Accuracy
    - Ensures consistent delivery of dose over shelf-life.

D. Microbiological Evaluation

1. Total Aerobic Microbial Count (TAMC)
2. Total Yeast and Mold Count (TYMC)
3. Pathogen Testing (e.g., *S. aureus*, *P. aeruginosa*, *E. coli*)

- Particularly important for aqueous or inhalation aerosols.

Stability Studies

A. Purpose

- To determine the shelf-life, storage conditions, and chemical/physical stability.
- Ensures drug potency, propellant pressure, and performance characteristics over time.

B. Parameters for Stability Testing

1. Chemical Stability
    - Drug content, degradation products, and interaction with propellant/solvents.
2. Physical Stability
    - Appearance, phase separation, color change, sedimentation, foaming properties.
3. Propellant Stability
    - Maintenance of pressure and delivery consistency.
4. Performance Stability
    - Spray pattern, particle size, metered dose, foam volume (if applicable).
5. Microbiological Stability
    - Growth of microorganisms under storage conditions.

C. Conditions for Stability Testing

- Accelerated Testing: 40°C ± 2°C / 75% RH ± 5% RH for 6 months (ICH guideline).
- Long-term Testing: 25°C ± 2°C / 60% RH ± 5% RH for 12–24 months.
- Photostability Testing: Evaluate effect of light exposure on chemical and physical stability.
- Freeze-Thaw Testing: Assess stability under extreme temperature changes.