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INDUSTRIAL PHARMACY - I

UNIT 3

TOPIC :

- **Pellets** : Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets



Pellets

- Pellets are small, free-flowing, spherical or semi-spherical solid particles, usually 0.5–1.5 mm in diameter, containing drug and excipients.
- They are used in multiparticulate drug delivery systems and can be filled into hard gelatin capsules, compressed into tablets, or used as sachets.
- Commonly used in oral dosage forms.

Advantages of Pellets

1. Uniform Drug Release
 - Each pellet acts as a single unit, allowing more predictable and reproducible drug release.
2. Reduced Risk of Dose Dumping
 - Multiparticulate nature distributes dose over GI tract; failure of one pellet doesn't release entire dose.
3. Improved Bioavailability
 - Smaller, spherical particles enhance dissolution rate and absorption.
4. Flexible Dosing
 - Pellets can be blended to create different strengths or combined for fixed-dose combinations.
5. Coating Possibilities
 - Easy to coat individual pellets for sustained release, delayed release, or enteric release.
6. Reduced Local Irritation
 - Distributed drug dose reduces GI irritation compared to single-unit tablets.
7. Enhanced Stability
 - Pellets can protect sensitive drugs when coated.
8. Ease of Handling and Processing
 - Free-flowing, spherical pellets facilitate capsule filling or compression into tablets.

Disadvantages of Pellets

1. Complex Manufacturing
 - Requires specialized equipment (extruder, spheronizer, fluidized bed).
2. Costly Production
 - Equipment and process complexity increase manufacturing cost.
3. Process Sensitivity
 - Pellet properties (size, shape, strength) depend heavily on process parameters (binder amount, moisture, spheronization speed).
4. Drug Limitations
 - Not suitable for drugs with poor flowability or low compressibility unless granulated properly.
5. Coating Requirement
 - Controlled-release or enteric formulations require additional coating steps, adding time and cost.
6. Potential for Friability
 - Poorly prepared pellets may crush or break, generating fines.

Formulation Requirements

A pellet formulation typically includes:

1. Drug substance
 - Should be compressible or granulatable.
 - Can be soluble or poorly soluble.
2. Binders
 - Improve cohesion of powder during pellet formation.
 - Examples: Povidone (PVP), HPMC, starch paste.
3. Filler or Diluent
 - Provides bulk and uniform size.
 - Examples: Microcrystalline cellulose (MCC), lactose, dicalcium phosphate.
4. Disintegrants (optional)
 - Promote rapid drug release from pellets.

- Examples: Croscarmellose sodium, sodium starch glycolate.
- 5. Plasticizers and Lubricants (if needed)
 - Ensure smooth processing and coating.
 - Examples: Magnesium stearate, PEG.
- 6. Coating polymers (optional)
 - For controlled, delayed, or targeted release.
 - Examples: Ethylcellulose, HPMC, cellulose acetate phthalate.

Important properties of pellet formulation:

- Good flowability for uniform filling.
- Adequate mechanical strength to resist crushing during processing.
- Low friability to prevent dust formation.

Pelletization Processes

Pelletization methods are classified into three major categories:

A. Solution or Melt Pelletization

- Principle: Powder or granules are agglomerated using a binding solution or molten binder to form spherical pellets.

Methods:

1. Melt Pelletization
 - Drug powder is mixed with a molten binder (e.g., waxes, PEG).
 - The mixture solidifies upon cooling into spherical pellets.
 - Advantage: No water required, suitable for moisture-sensitive drugs.
2. Solution Pelletization
 - Drug powder is sprayed with a binder solution.
 - Agglomerates form as the liquid evaporates.
 - Example binders: HPMC, PVP, gelatin.

B. Layering (Powder/solution layering)

- Principle: Pellets are built up layer by layer over a starter nucleus (e.g., sugar, microcrystalline cellulose).
- Methods:
 1. Powder layering – fine drug powder is applied to cores with binder solution.
 2. Solution layering – drug dissolved in solvent is sprayed onto cores, forming solid layers.
- Advantage: Controlled drug loading, suitable for multiparticulate or modified-release pellets.
- Equipment: Rotary pelletizer / coating pan.

C. Granulation and Spheronization

- Principle: Powder is wet-massed, extruded into rods, then cut and rounded into spherical pellets.

Steps:

1. Massing – Powder is mixed with binder solution to form a wet mass.
 2. Extrusion – Wet mass is forced through a die to form cylindrical extrudates.
 3. Spheronization – Extrudates are placed in a spheronizer to round into spheres.
 4. Drying – Pellets are dried to remove moisture.
- Advantages:
 - Produces uniform, dense, spherical pellets.
 - Suitable for controlled-release and multiparticulate dosage forms.
 - Equipment: Extruder, spheronizer, fluidized bed dryer.

D. Other Methods

1. Spray Congealing / Spray Cooling
 - Drug or polymer melted and sprayed into cooling chamber, forming solid pellets.
 - Useful for thermolabile or oily drugs.
2. Balling / Rolling
 - Powder is rolled in a pan with binder to form spherical agglomerates.
 - Also called dragee or pellet balling.
 - Simple, low-cost method for large-scale production.

Equipment by Pelletization Method

A. Extrusion-Spheronization Equipment

1. Mixer / Granulator
 - Purpose: Mixes drug powder with binder solution to form a wet mass.
 - Types: High-shear mixer, planetary mixer.
2. Extruder
 - Purpose: Forms cylindrical extrudates from the wet mass.
 - Types: Screw extruder, ram extruder.
 - Parameters: Die diameter and extrusion speed control pellet size.
3. Spheronizer
 - Purpose: Converts extrudates into spherical pellets.
 - Components: Rotating plate with friction cross-hatch or radial grooves.
 - Parameters: Rotation speed, residence time, and plate design control sphericity and uniformity.
4. Dryer
 - Purpose: Removes moisture from wet pellets to final 12–16% moisture content.
 - Types: Fluidized bed dryer, tray dryer, rotary dryer.

B. Layering / Powder Coating Equipment

1. Rotary Coating Pan

- Purpose: Layer drug powder or solution onto starter nuclei.
- Features: Rotating pan with spray nozzles, baffles for uniform layering.

2. Spray System

- Purpose: Spray binder solution or drug solution for uniform adhesion.

3. Fluidized Bed Coater / Pelletizer

- Purpose: Simultaneously layer and dry pellets in a fluidized air stream.
- Advantage: Good particle size uniformity, faster drying.

C. Balling / Rolling Equipment

1. Drum / Pan Pelletizer

- Purpose: Forms pellets by rolling powder with binder in a pan or rotating drum.
- Features: Adjustable rotation speed and pan angle for optimal pellet growth.

2. Spray Nozzle

- Purpose: Apply binder solution to aid agglomeration.

D. Spray Congealing / Melt Pelletization Equipment

1. Spray Congealer

- Purpose: Sprays melted drug or polymer into a cooling chamber, forming solid pellets.

2. Cooling Chamber

- Maintains low temperature to solidify molten droplets quickly.

3. Collection System

- Separates and collects solidified pellets.