

Pharmaceutics Notes for Chapters 5 and 6 (D.Pharm, ER-2020)

Chapter 5: Tablets

1. Introduction

- **Definition:** Tablets are solid oral dosage forms containing active pharmaceutical ingredients (APIs) with or without excipients, prepared by compression or molding.
- **Advantages:**
 - Accurate dosing, ease of administration, patient compliance.
 - Stable, portable, cost-effective.
- **Disadvantages:**
 - Unsuitable for patients with swallowing difficulties.
 - Potential drug degradation in the gastrointestinal tract.

2. Types of Tablets

- **Oral Tablets:**
 - Uncoated (e.g., Paracetamol).
 - Coated: Sugar-coated, film-coated, enteric-coated (e.g., Aspirin enteric-coated).
- **Chewable Tablets:** For chewing (e.g., Digene antacid).
- **Effervescent Tablets:** Dissolve in water, release CO₂ (e.g., Vitamin C tablets).
- **Sublingual/Buccal Tablets:** Dissolve under tongue/cheek (e.g., Nitroglycerin).
- **Controlled-Release Tablets:** Extended drug release (e.g., Metformin SR).
- **Lozenges:** Slow-dissolving (e.g., Strepsils).
- **Tablet Triturates:** Small, molded for potent drugs (e.g., homeopathic tablets).

3. Formulation

- **Components:**
 - **API:** Therapeutic agent (e.g., Ibuprofen).
 - **Excipients:**
 - **Diluents:** Add bulk (e.g., Lactose, Microcrystalline Cellulose).
 - **Binders:** Promote adhesion (e.g., Starch, PVP).
 - **Disintegrants:** Aid breakup (e.g., Croscarmellose Sodium).
 - **Lubricants:** Reduce friction (e.g., Magnesium Stearate).
 - **Glidants:** Improve flow (e.g., Colloidal Silicon Dioxide).
 - **Colorants/Flavorants:** Enhance appearance/taste (e.g., Titanium Dioxide).
- **Steps:**
 - Mix API and excipients.
 - Granulate (wet/dry) for flow and compressibility.
 - Compress using a tablet press.

4. Manufacturing

- **Methods:**
 - **Direct Compression:** Mix and compress (for stable APIs).
 - **Wet Granulation:** Use liquid binder, dry, compress (for poor-flow powders).
 - **Dry Granulation:** Compact into slugs/roller compaction, mill, compress (for moisture-sensitive drugs).
- **Equipment:** Single punch/rotary tablet press, granulators, dryers.
- **Defects:**
 - Capping: Tablet splits at top.
 - Lamination: Splits into layers.
 - Sticking: Adheres to punch.
 - Mottling: Uneven color.

5. Evaluation

- **Official Tests:**
 - Weight Variation: Ensures uniform weight.
 - Content Uniformity: Consistent API content.
 - Hardness: Resistance to crushing (e.g., Monsanto tester).
 - Friability: Durability (e.g., Roche Friabilator, <1% loss).
 - Disintegration: Breakup time (e.g., <15 min for uncoated tablets).
 - Dissolution: Drug release rate (e.g., USP apparatus).
- **Non-Official Tests:** Appearance, thickness, diameter.

6. Tablet Coating

- **Purpose:**
 - Protect drug from moisture/light.
 - Mask taste/odor.
 - Control release (e.g., enteric coating).
- **Types:**
 - Sugar Coating: Aesthetic, taste-masking (e.g., Vitamin tablets).
 - Film Coating: Thin polymer layer (e.g., HPMC for Ibuprofen).
 - Enteric Coating: Resists gastric acid (e.g., Pantoprazole).
- **Equipment:** Coating pans, fluid bed coaters.
- **Defects:**
 - Orange peel: Rough surface.
 - Bridging: Coating fills logos.
 - Cracking: Coating splits.

7. Practical Applications

- **Syllabus Link:** Prepare and evaluate tablets (e.g., Paracetamol) for weight variation, hardness, disintegration (page 8).

- **Use:** Most common dosage form in hospitals/community pharmacies due to stability and versatility.
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Chapter 6: Capsules

1. Introduction

- **Definition:** Capsules are solid oral dosage forms where drugs are enclosed in a soluble shell (gelatin or plant-based).
- **Advantages:**
 - Masks taste/odor.
 - Flexible for multiple drugs.
 - Easy to swallow.
- **Disadvantages:**
 - Higher cost than tablets.
 - Unsuitable for highly water-soluble/hygroscopic drugs.

2. Types of Capsules

- **Hard Gelatin Capsules:** Two parts (body/cap) for powders/granules (e.g., Amoxicillin).
- **Soft Gelatin Capsules:** Sealed, for liquids/semi-solids (e.g., Vitamin E).
- **Modified-Release Capsules:** Delayed/sustained release (e.g., Omeprazole).

3. Formulation

- **Components:**
 - **API:** Therapeutic agent.
 - **Excipients:**
 - Diluents: Add bulk (e.g., Lactose, Mannitol).
 - Lubricants/Glidants: Improve flow (e.g., Magnesium Stearate, Talc).
 - Disintegrants: Aid release (e.g., Starch).
 - **Capsule Shell:**
 - Hard gelatin: Animal-derived.
 - Soft gelatin: Gelatin with plasticizers (e.g., glycerin).
 - Vegetarian: HPMC/starch-based.
- **Considerations:** Particle size, flowability, drug-shell compatibility.

4. Manufacturing

- **Hard Gelatin Capsules:**
 - Mix API/excipients.
 - Fill capsules (manual/automated machine).
 - Lock cap and body.

- **Equipment:** Capsule-filling machines.
- **Soft Gelatin Capsules:**
 - Prepare liquid/semi-solid fill.
 - Encapsulate via rotary die process.
 - Dry and polish.
 - **Equipment:** Softgel encapsulation machines.
- **Challenges:** Uneven filling, shell leakage, deformation.

5. Evaluation

- **Official Tests:**
 - Weight Variation: Uniform capsule weight.
 - Content Uniformity: Consistent API content.
 - Disintegration: Dissolution time (e.g., <30 min for hard capsules).
 - Dissolution: Drug release rate.
- **Non-Official Tests:** Appearance, shell integrity, fill consistency.
- **Practical Link:** Prepare/evaluate capsules (e.g., Tetracycline) for weight variation, disintegration (page 8).