Capsules

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Definition:

- Capsules are solid dosage forms in which medicinal substances are enclosed in a small shell made of gelatin or other suitable materials.
- Capsules are taken orally and are a popular alternative to tablets due to their ease of swallowing, tastelessness, and ability to mask unpleasant odors and tastes.

Classification:

- Capsules are broadly classified into two types:
    - **Hard gelatin capsules (HGCs)**: Made of two rigid gelatin shells (body and cap) that are filled with powders or granules.
    - **Soft gelatin capsules (SGCs)**: Made of a single soft, flexible shell, used for enclosing liquids, suspensions, or semi-solids.

Advantages:

- Improved patient compliance
- Better bioavailability (especially for oily or poorly soluble drugs)
- Protection of sensitive drugs from environmental conditions
- Customizable in color, size, and imprint

Disadvantages:

- Not suitable for aqueous formulations (especially in hard gelatin capsules)
- Hygroscopic drugs can affect the shell integrity
- Requires specialized equipment for large-scale manufacturing
- Cost may be higher than tablets

Introduction to Hard Gelatin Capsules

Definition:

- Capsules are solid dosage forms in which the drug substance (active pharmaceutical ingredient, API) and excipients are enclosed in a soluble container or shell.
- Hard gelatin capsules (HGCs) are two-piece shells consisting of a body and a cap.



Composition of Shell:

- Typically composed of gelatin, water, and small quantities of opacifying agents (e.g., titanium dioxide), colorants, and/or dyes.

Advantages:

- Ideal for delivering powdered, granular, or pelletized formulations.
- Mask unpleasant tastes and odors.
- Offer versatility in drug formulation (can accommodate multiple APIs or modified-release beads).
- Generally, have a faster disintegration time than tablets (leading to quicker onset of action).

Disadvantages:

- More expensive manufacturing process than simple tableting.
- Potential for capsule tampering (though modern banding and sealing can mitigate this).
- Sensitivity to moisture and humidity.

Production and Filling of Hard Gelatin Capsules

Overview

- Hard gelatin capsules are two-piece cylindrical containers composed of:
    - **Cap**: The shorter piece.
    - **Body**: The longer piece that holds the fill material.
- These capsules are manufactured empty and later filled with medication using manual or automated processes.

Raw Materials:

1. **Gelatin:** Derived from animal collagen (commonly bovine or porcine sources), gelatin provides the structural matrix.
2. **Plasticizers:** Substances like glycerin or sorbitol are added to enhance flexibility and prevent brittleness.
3. **Water:** Acts as a solvent and plasticizer.

Steps in Production:

A. Shell Manufacturing:

1. **Preparation of gelatin solution**: A 30–40% gelatin solution is prepared using gelatin, plasticizers (like glycerin or sorbitol), preservatives, and colorants.

2. **Dipping**: Stainless steel mold pins (body and cap pins) are dipped into the gelatin solution to form a film.
3. **Rotation**: The pins rotate to ensure uniform film thickness.
4. **Drying**: The gelatin-coated pins are passed through a drying chamber to remove moisture.
5. **Stripping**: The dried shells are stripped off the pins.
6. **Trimming**: Edges of the shells are trimmed to correct length.
7. **Joining**: The cap and body are joined to form empty capsules.

B. Capsule Filling:

1. **Rectification**: Aligning all capsules in the same direction.
2. **Separation**: The cap is removed from the body.
3. **Filling**: Medicament (usually in powder or granule form) is filled into the body.
4. **Rejoining**: The cap is placed back onto the filled body.
5. **Ejection**: Filled capsules are ejected and collected.

Filling Techniques:

- Manual filling (for small-scale batches)
- Semi-automatic machines
- **Fully automatic capsule filling machines**: Suitable for industrial scale.

Types of Fill Materials:

- Powders
- Pellets
- Granules
- Mini-tablets
- **Non-aqueous liquids or pastes** (with special sealing)

Raw Material for Shell

- The capsule shell, whether for hard or soft gelatin capsules, requires specific raw materials to ensure proper mechanical properties, biocompatibility, and stability.

Key Raw Materials:

A. Gelatin:

- **Source**: Derived from collagen of animal tissues (usually bovine or porcine skin and bones).

- **Types**:
  - **Type A gelatin**: From acid-treated precursor, pH 3.5–5.0
  - **Type B gelatin**: From alkaline-treated precursor, pH 4.8–5.5
- **Function**: Forms the basic matrix of the capsule shell.

B. Plasticizers:

- Provide flexibility and reduce brittleness.
- **Common types:**
  - Glycerin
  - Sorbitol
  - Propylene glycol (less commonly)

C. Colorants and Opacifiers:

- Improve aesthetic appeal and aid in product identification.
- **Examples:**
  - FD&C dyes
  - Titanium dioxide (used as an opacifier)

D. Preservatives:

- Prevent microbial growth.
- **Example:**
  - Methylparaben
  - Propylparaben

E. Water:

- Acts as a solvent for gelatin and affects shell quality.
- Purified water is used for dissolution.

F. Other optional ingredients:

- Flavoring agents (to mask taste)
- Sweeteners (for chewable capsules)

Finishing of Capsules

- After the capsules are filled, they undergo finishing processes to enhance their appearance, ensure cleanliness, and prepare them for packaging.

Purpose of Finishing:

- To remove powder residues
- To polish capsules
- To enhance consumer appeal
- To prepare for packaging and inspection

Finishing Processes:

A. Cleaning:

- Removes powder or formulation residues from capsule surfaces.
- **Methods**:
  - **Brushing**: Capsules pass through a rotating soft brush system.
  - **Cloth cleaning**: Capsules tumble over soft cloths that clean the surface.
  - **Vacuum cleaning**: High-speed vacuum systems remove surface dust.
  - **Compressed air**: Used to blow off loose powder.

B. Polishing:

- Gives the capsule a shiny and smooth finish.
- **Equipment**:
  - **Pan polishers**: Capsules are rotated in polishing pans lined with soft cloth.
  - **Buffing wheels**: Rotating wheels buff and polish capsule surfaces.
  - **Polishing with anti-static agents**: Prevents powder from re-adhering due to electrostatic charges.

C. Inspection:

- Manual or automated systems check for:
  - Cracks or splits
  - Deformation
  - Color inconsistencies
  - Improper sealing (if required)
  - Foreign particles

D. Sorting:

- Capsules are sorted based on size, color, or defects using:
  - Visual inspection systems
  - Automated optical sorters
  - Weight sorters

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