

Hard Gelatin Capsules

Capsules

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)

Size of Capsules

- Hard gelatin capsules are available in various sizes, ranging from **000 (largest)** to **5 (smallest)**.
- The choice of size depends on:
 - The dose of the drug.
 - Bulk density of the formulation.
 - Patient acceptability.

Size	Capacity (mg)	Volume (mL)
000	~950 – 1350	1.37

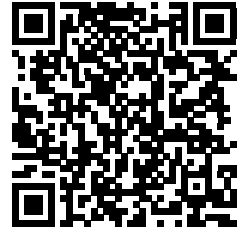


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