Capsules

Introduction to Capsules

- Capsules are solid oral dosage forms in which one or more active pharmaceutical ingredients (APIs) and excipients are enclosed within a gelatin or non-gelatin shell.
- They are widely used in the pharmaceutical industry due to their versatility, ease of swallowing, and ability to mask unpleasant tastes or odors.



Types of Capsules

Capsules are broadly classified into two main types:

1. **Hard Gelatin Capsules (HGCs):**
   - Consist of two pre-fabricated cylindrical shells (a body and a cap).
   - Filled primarily with dry powders, pellets, or granules.
   - Shells are made of gelatin (animal origin) or HPMC (vegetarian alternative).
2. **Soft Gelatin Capsules (Softgels):**
   - Made from a single, flexible, and hermetically sealed shell.
   - Usually filled with liquids, semi-solids, or suspensions.
   - Commonly used for oils, vitamins, and lipid-soluble drugs.

Advantages of Capsules

- Easy to swallow and aesthetically pleasing.
- Effectively mask unpleasant taste or odor.
- Suitable for poorly compressible drugs.
- Flexible in dosing and can contain solid, liquid, or semi-solid formulations.
- Capsule shells can be modified for controlled or delayed release.

Limitations

- Sensitive to moisture and heat.
- Not ideal for highly soluble salts (can cause rapid release and irritation).

- Gelatin-based capsules are unsuitable for strict vegetarians or vegans (unless alternatives are used).

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 Capsule Shell

- Typically composed of:
  - Gelatin
  - Water
  - Small quantities of:
    - Opacifying agents (e.g., titanium dioxide)
    - Colorants and/or dyes

Advantages

- Ideal for powders, granules, and pellets.
- Mask taste/odor, offer formulation flexibility.
- Faster disintegration than tablets.

Disadvantages

- Higher production cost than tablets.
- Susceptible to tampering and moisture.

Production of Hard Gelatin Capsule Shells

Raw Materials

1. **Gelatin** – Derived from animal collagen (bovine or porcine); provides structural matrix.

2. **Plasticizers** – e.g., glycerin or sorbitol; enhance flexibility and prevent brittleness.
3. **Water** – Acts as a solvent and plasticizer.

Process Steps

1. **Gelatin Solution** – Gelatin + water + additives, controlled temperature/viscosity.
2. **Dipping** – Pins dipped to form body and cap.
3. **Rotation & Drying** – Gelatin film spread and dried (20–25 °C, 40–50% RH).
4. **Stripping & Trimming** – Dried shells removed and cut.
5. **Joining & Sorting** – Body and cap assembled; defects removed.

Capsule Sizes

Size	Capacity (mg)	Volume (mL)
000	950–1350	1.37
00	650–1000	0.95
0	390–910	0.68
1	300–600	0.50
2	200–450	0.37
3	150–300	0.30
4	120–180	0.21
5	60–130	0.13

Filling, Finishing, and Special Techniques

Filling Methods

1. **Powders and Granules** – Filled using tamping or auger mechanisms.
2. **Pellets** – Pre-formed units are placed inside the capsule.
3. **Liquids and Semi-solids** – Require sealing to prevent leakage.
4. **Tablet-in-Capsule** – Combines a pre-made tablet and powder within a capsule.

Finishing Techniques

- **Brushing** – Capsules are rotated against soft brushes to remove dust.
- **Cloth Polishing** – Capsules pass through a polishing pan lined with soft fabric.

Special Techniques

- **Band Sealing** – Gelatin band applied to prevent tampering or leakage.

- **Spray Coating** – Capsules coated with enteric or controlled-release polymers.
- **Liquid-Filled Capsules** – Require advanced sealing techniques.

Common Defects & Prevention

Defect	Cause	Prevention
Cracks	Over-drying, brittleness	Adjust plasticizer/drying
Deformation	High humidity	Controlled storage
Leaks	Poor sealing	Improved sealing techniques
Uneven Thickness	Dipping inconsistency	Viscosity/temp control
Separation	Poor fit	Assembly inspection

Quality Control Tests

In-Process

- Weight variation, moisture content, appearance check

Final Tests

- Disintegration, dissolution, content uniformity
- Stability testing, microbial testing, seal integrity

Soft Gelatin Capsules (Softgels)

Introduction

- Softgels are one-piece, pliable capsules that enclose liquid or semi-solid formulations.
- Commonly used in pharmaceuticals, nutraceuticals, and cosmetics.



Key Features

- Made of a soft, elastic gelatin-based shell.
- Suitable for liquid/semi-solid drugs.
- Protects against light, moisture, and oxidation.

Advantages

- Masks unpleasant taste/odor.

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