

# 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                  |
|-------------------------|--------------------------|-----------------------------|
| <b>Cracks</b>           | Over-drying, brittleness | Adjust plasticizer/drying   |
| <b>Deformation</b>      | High humidity            | Controlled storage          |
| <b>Leaks</b>            | Poor sealing             | Improved sealing techniques |
| <b>Uneven Thickness</b> | Dipping inconsistency    | Viscosity/temp control      |
| <b>Separation</b>       | 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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