PHARM.D • YEAR 3

Pharmaceutical Formulations

CHAPTER 3

Hard and Soft Gelatin Capsules

PPT CHAPTER COVER



DOCTOR OF PHARMACY

CAPSULES — DEFINITION AND CLASSIFICATION

Definition

- Solid dosage form with drug substance (API) and excipients enclosed in a small soluble shell, usually gelatin or other suitable materials.
- Taken orally; easy to swallow and can mask unpleasant tastes/odours.

Classification

- Hard gelatin capsules (HGCs): two rigid shells (body + cap) filled with powders or granules.
- Soft gelatin capsules (SGCs): single soft, flexible shell used for liquids, suspensions or semi-solids.

Key advantage

- Improve patient compliance compared with tablets.

Hard gelatin capsule (HGC)

Two-piece rigid shell



Typically filled with powders or granules

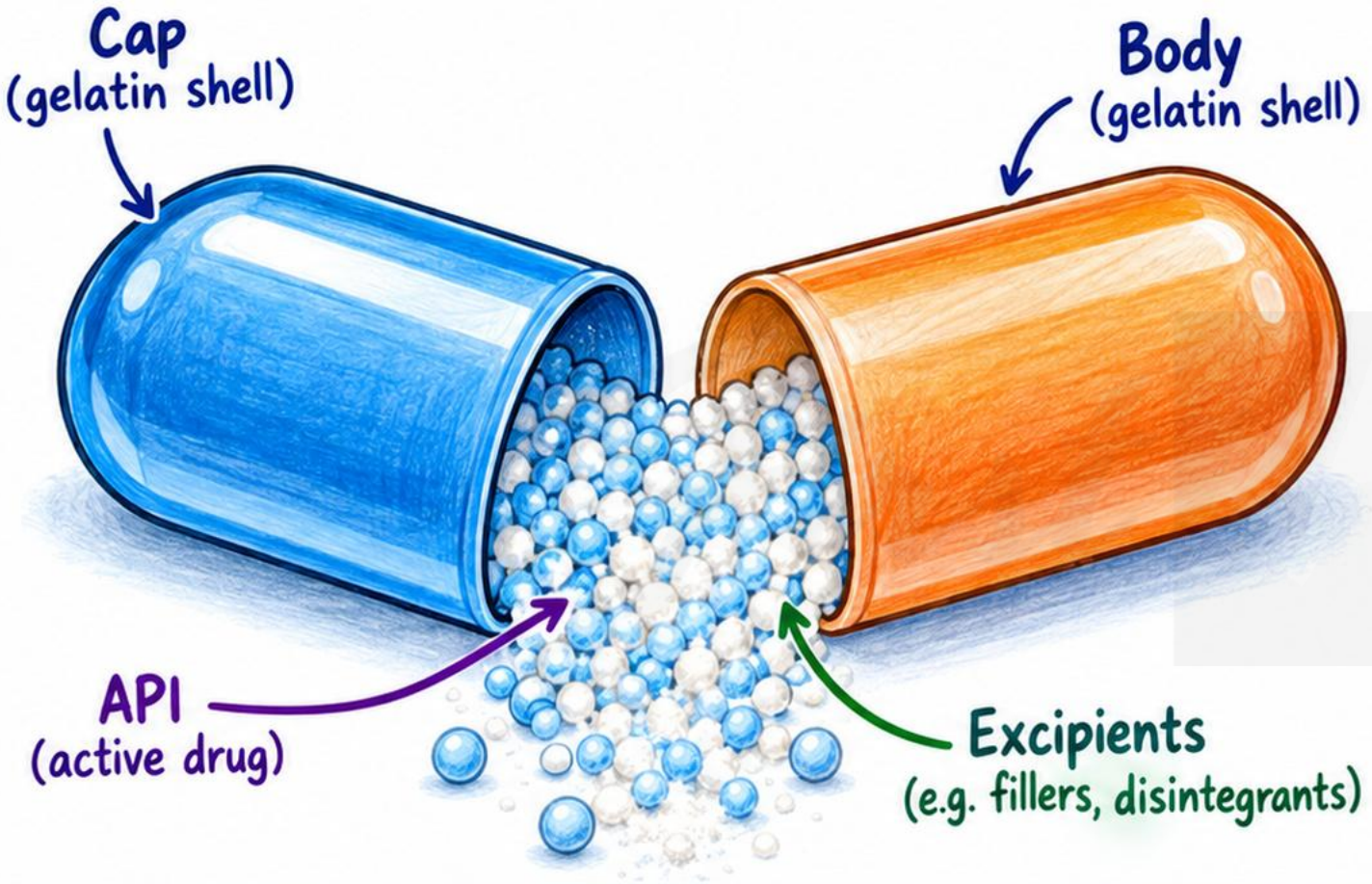
Soft gelatin capsule (SGC)

Single soft, flexible shell



Typically filled with liquids, suspensions or semi-solids

WHY CHOOSE A CAPSULE?



Taste masking
Hides unpleasant tastes/odours

Easy to swallow
Smooth shell improves patient compliance

Dose flexibility
Wide range of drug loads

Fill versatility
Can contain powders, granules, liquids, suspensions or semi-solids

CONSIDER LIMITATIONS

- Not suitable for aqueous formulations (especially hard shells)
- Hygroscopic drugs can affect shell integrity
- Cost may be higher than tablets

HARD CAPSULE SHELL — CAP AND BODY

TWO-PIECE GEOMETRY



Cap (shorter piece)

Locking fit (friction fit)

Body (longer piece, holds the fill material)

SHELL MATERIALS



Gelatin
- from animal collagen (e.g. bovine or porcine)

OR



Suitable non-gelatin polymers
- e.g. HPMC or pullulan

SIZES

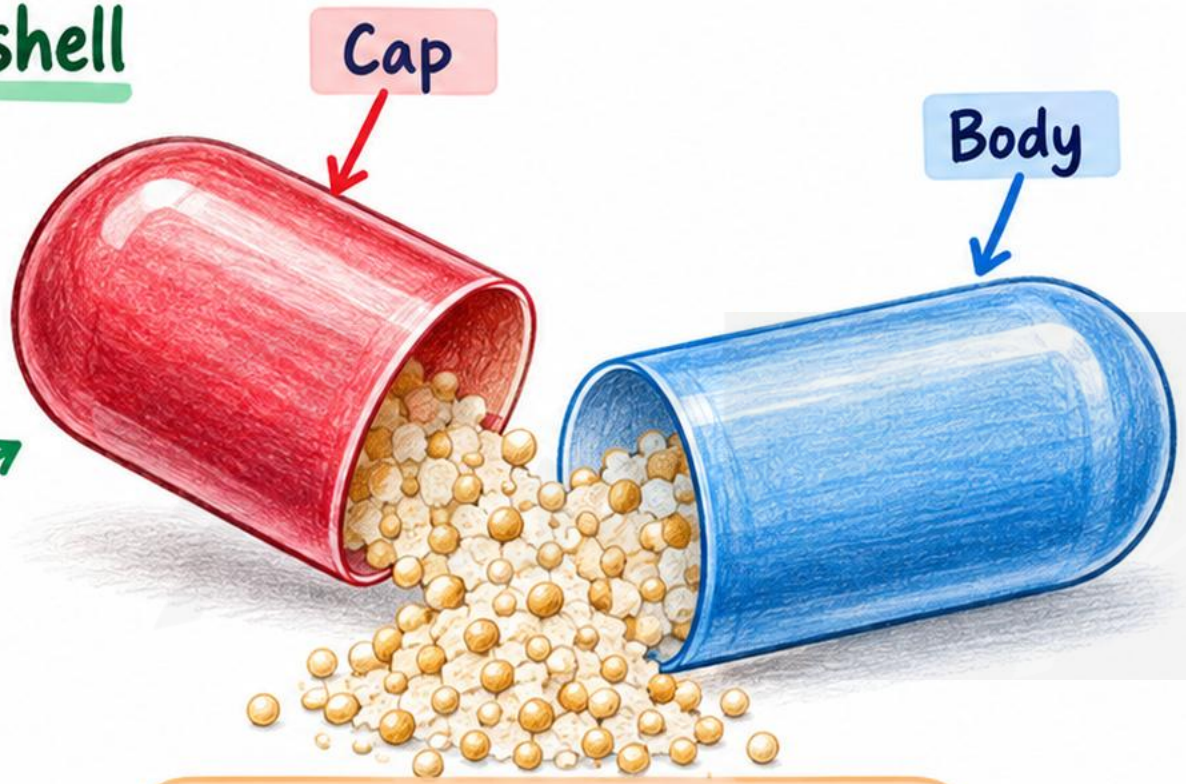


000 00 0 1 2 3 (common sizes)

HARD CAPSULES – ADVANTAGES AND LIMITATIONS

Composition of shell

- Gelatin
- Water
- Colourants / opacifying agents (as permitted)



Fill: powders, granules, pellets and some non-aqueous fills

Advantages

- Suitable for powders, granules, pellets
- Mask unpleasant tastes and odours
- Versatile (e.g. multiple APIs or modified-release beads)
- Generally faster disintegration than tablets

Limitations

- More expensive to manufacture than simple tableting
- Potential for tampering
- Sensitive to moisture and humidity

Protects fill from brittleness, softening and incompatibility.

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