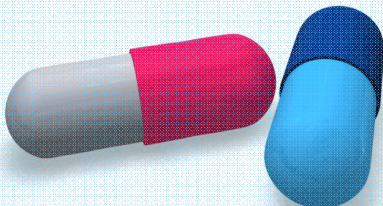


Capsules



1

Objectives

- Differentiate between hard and soft gel caps.
- Study different capsule excipients, shapes and sizes.
- Understand capsules manufacturing and quality control testing.



2

Advantages of capsules as a dosage form:

1. Capsules may be used to mask the unpleasant taste or appearance of a drug.
2. Capsules allow powders to be dispensed in an uncompressed form, thus allowing for quicker dissolution and absorption of the drug as compared to tablets.
3. They offer the pharmacist a versatility to prepare any dose desired useful. Filling very large capsules with higher doses of drug may find much utility for animal use.



3

4. They may be easier than tablets for some people to swallow.
5. Filled capsules are very popular as clinical trial material and the compounding pharmacist may be asked to prepare them.



4

Disadvantages of Capsules

1. The number of suppliers of shells is limited.
2. Filling equipment is slower than tableting
3. More costly than the cost of producing tablets.



5

Capsules

- Solid dosage form in which medications or inert substances are enclosed in hard or soft gelatin capsules.
- Usually taken intact but may be opened and mixed with liquid under the pharmacist supervision.
- Is the dosage form of choice during clinical trials.

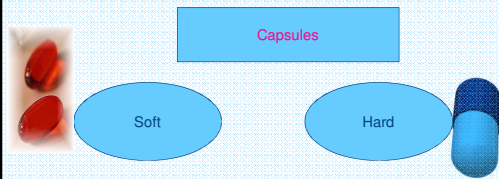


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Capsules

Capsules

- Capsule use
 - Commercial medications
 - Clinical trials
 - Extemporaneous compounding



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Hard Gel Capsules



8

Hard gelatin capsules

- Cap & Body.
- Gelatin, water, sugar, dye, and sometimes titanium dioxide (renders shell opaque).
- Gelatin:
 - Made by partial hydrolysis of collagen obtained from skin, connective tissue & bones of animals.
 - Fine powder, shreds, flakes, sheets
- Moisture:
 - Hard gel capsule shell has 13-16% moisture.
 - Capsules should be stored at conditions of intermediate humidity.



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Hard gelatin capsules

- Gelatin absorbs cold water. Capsules may be dipped in cold water before administration.
- **Why?**
- The shell dissolves in hot water and in warm gastric fluid, and exposes its content to GIT fluid.
- Gelatin is a _____, so it gets digested in GIT.



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Reading

- The manufacturing of hard gel capsule shell
- Pg 241-242

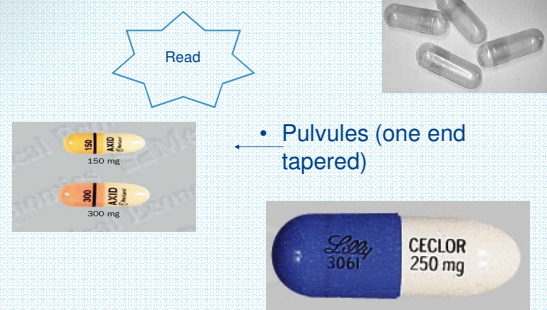
[manufacturing](#)



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Capsules shapes

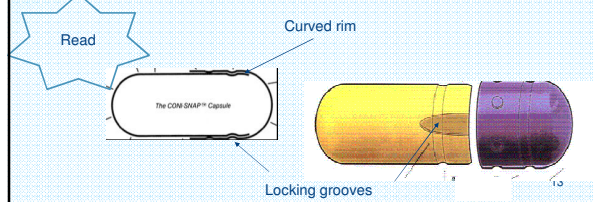
Most commercial capsules have rounded ends.



Capsules Shapes

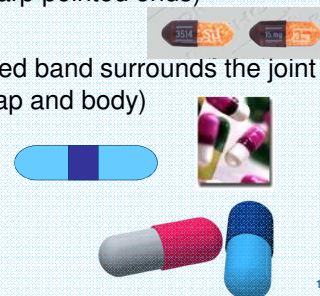
Coni-snap capsule: has grooves to lock the body and the cap after closing capsules

And curved rim to prevent denting and splitting problems that are common with straight rims



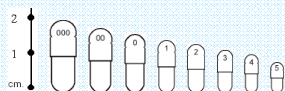
Capsules shapes

- Spansules (sharp pointed ends)
- Kapseal (colored band surrounds the joint between the cap and body)



Capsule size

- Capsule size
- Human size 5-000
- Size 5 the smallest
- Can be filled with 65 mg-1.4 g
- Depends on the weight and the density.
- Use smallest size that will properly hold your content.



Formulation

- Excipients :
 - Diluent (filler to add bulkiness to the medication) may be added: e.g. lactose, microcrystalline cellulose
 - Occasionally disintegrant is added e.g. starch to enhance granules break up and spreading after shell opening in the stomach
 - Glidant &/or lubricant: (enhance powder flow and lubricates the machine parts) silicon dioxide, Mg stearate..(0.25-1%).
 - Surfactant (Na lauryl sulfate) to facilitate wetting of the capsule content by the gastrointestinal fluid.



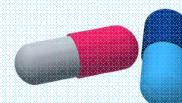
Formulation

- Capsules may be filled by
 - Separate chemicals
 - Controlled release medications.
 - Extemporaneous preparations
- Oils, pastes & suspensions may be filled in hard gel cap.
- On large scale: liquids are filled in soft gel capsule.



Filling capsules

- On a small scale :
 1. (the punch method).
 2. Hand operating machines fill.(see figure 7.9 in your text book pg.248)
- On large scale
(see figure 7.6 in your text book) Pg.244

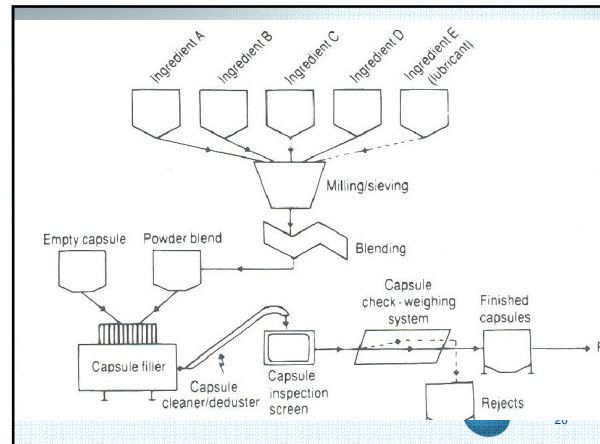


Capsule sealing

- Capsule sealing:
 1. Sometimes colored band of gelatin is used (Kapseals).
 2. Heat welding
 3. Liquid wetting agent that lowers melting point in the contact area of cap and body.



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Cleaning

- Cleaned individually
- Vacuum



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Soft gel capsule

- The shell is made of
 - Plasticized gelatin (addition of glycerin, sorbitol and propylene glycol)
 - Water: Higher percentage than hard gel
 - Titanium dioxide to render it opaque
 - Preservative.
 - Methylparaben
 - Only commercially prepared.

Why?



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Soft gel capsule

- The soft gel capsule can be filled with
 - Solid: suspension, dry powder, pellets, small tablets.
 - Pastes.
 - Liquid.



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Soft Gel Capsule

- Liquids Cannot include :
 - Water > 5%, or low molecular weight water soluble volatile organic compound as alcohol.



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Testing



1- Disintegration:

One capsule in basket, 37 °C.

A capsule has to disintegrate to soft mass.

2- Dissolution: Time needed for the content of the capsule to dissolve in the dissolution media. Capsule may be tested intact or emptied if gelatin interferes.



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Testing

3-Dosage form uniformity:

Weight variation &/or Content Uniformity:

A- Weight variation

– *Hard gel:* The **intact** capsule and the **emptied shells** of 10 capsules are individually weighed to determine the net content.

– *Soft gel weight content:* determined by weighing the **intact** and **emptied** capsules after washing.



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Testing

B- Content Uniformity: Determination of the active ingredient content in the capsule.

- Unless otherwise indicated the amount of **active ingredient and the weight variation** should fall within 85%-115% for the tested 10 capsules. RSD < 6%



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Testing

- 4-Stability testing: The stability of the active ingredient as well as the effect of temperature, humidity and light on the capsule shell.



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Oral administration of solid dosage form

- With water
- If capsules need to be opened it should be done under pharmacist supervision.
- Relevance to food is very important.



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