



Capsules and their types

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Capsules

1- Introduction

Capsules are solid dosage form intended for delivery of drug of various other dosage forms enclosed in a soluble shell of gelatin, starch or similar material and they are intended to be swallowed as a whole orally.

Capsules can be filled with dry material , semi solid and liquids that are non solvents of gelatin.

The basic empty capsule shells are made from a mixture of gelatin, sugar or water and are clear, odorless and essentially tasteless.



2- Gelatin

According to U.S.P, gelatin is a product obtained by the partial hydrolysis of collagen obtained from the skin, white connective tissues and bones of animals.



3- Types of Gelatin:

Type A

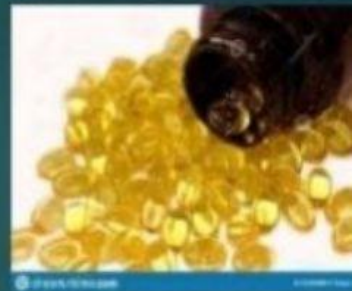
It is obtained by acid treatment of animal skin. Mostly type A gelatin is used in composition.

Type B

It is obtained by alkaline treatment of bones.

4- Properties of Gelatin

- It is soluble in biological fluids.
- Texture is stable as it has good mechanical properties.
- Flow properties are good at elevated temperature.
- It has high bloom strength. So, have high quality of gelatin. Bloom strength is a parameter to determine quality and grade of gelatin. It is defined as weight in grams required to depress a gelatin sheet to a defined depth.
- Gelatin is stable in air when dry but it subjects to microbial decomposition when it becomes moist or when is maintained in aqueous solution.
- Soft gelatin capsules have high moisture content than hard gelatin capsule.



5- Storage of Gelatin:

- If stored in high humid environment, additional moisture is absorbed by the capsules and they may become distorted and lose their rigid shape.
- If stored in highly dried environment, so the moisture present in gelatin capsule may be lost and the capsule may become brittle and may crumble when handled.
- Therefore, it is desired to maintain hard gelatin capsules in an environment free from excessive humidity or dryness.

6- Advantages of Capsules:

1. Capsules may be used for dispersing solid, semi-solid and liquid drugs.
2. They are easy to swallow than tablets.
3. Less adjuncts are necessary than for tablets.
4. It has low cost as less manufacturing steps are involved.
5. Liquid preparations like vitamins can be delivered by soft gelatin capsule.
6. Avoidance of the contact with the unpleasant odor and flavour of medicine.
7. They are attractive as same or different colours of cap and body.
8. Shells are physiologically inert and are easily and quickly degraded and digested in stomach.
9. Contact time in mouth is less so easily swallowed.
10. More rapid response of capsule have more bioavailability.

7- Disadvantages of Capsules:

1. If filling is not improper, then dose variation.
2. They can be used for aqueous or alcoholic solutions as they will attack the shell.
3. Capsules are expensive than the tablets regarding complete preparation as additional material in capsule is required.
4. Deliquescent and hygroscopic substances can't be capsulated.
5. Stability issue specially in case of soft gelatin capsules. If sealing is not proper, then liquid will leak out of capsule.
6. Salts which are very readily soluble should not be capsulated as sudden release will cause the irritation.
7. Insoluble substances such as some bismuth salts are reported to cause formation enteroliths In the intestine when administered in the form of capsules.

8- Size of Capsules

<u>Size of capsules</u>	<u>Solid capacity (mg)</u>	<u>Liquid capacity (ml)</u>
5	65	0.13
4	130	0.21
3	195	0.30
2	260	0.37
1	335	0.50
0	490	0.68
00	650	0.95
000	975	1.37

9- Types of Gelatin Capsules :

There are 2 types of gelatin capsules;

- Hard gelatin capsules
- Soft gelatin capsules

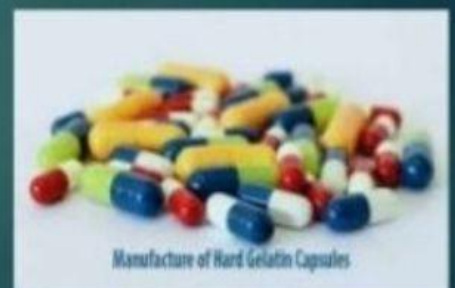
9.1. Hard Gelatin Capsules:

These capsules are formed from gelatin containing sugar and water in appropriate proportions. Hard gelatin capsules are made up of capsule body and a shorter cap. The two parts overlap when joined with the cap fitting snugly over opened side of capsule body.

9.1.1 Types of Hard gelatin Capsules:

Hard gelatin capsules mainly include:

- Snap-Fit
- Coni-Snap
- Coni-Snap Supro



- **Snap-fit:**

These are plain surface capsules having no grooves. Snap fit capsules are bearing the disadvantage of silting and denting due to contact between cap and body during sealing process because the rim of capsule body is straight.

- **Coni snap:**

These capsules have grooves on their body and cap both. The location of grooves are on such places that the capsule is locked. More than 1 groove may be present. Grooves may be dotted or round etc.

- **Coni snap Supro:**

These capsules also have grooves but their differences with conic snap lies in length of cap and body. One or more grooves may be present. Slit indentations prevent premature opening. Separation of two parts is difficult and contribute to capsule integrity.

9.1.2 Manufacturing of Hard Gelatin Capsules:

Manufacturing involves following steps, these are

- | | |
|--------------------------------|-------------------------------|
| 1-Preparation of gelatin shell | 2-Filling of capsules |
| 3-Sealing of capsules | 4-Imprinting as optional step |
| 5-Cleaning of capsules | |
| 6-Polishing of Capsules | |

1- Preparation of Gelatin Shell:

1. Gelatin solution will be prepared by dissolving gelatin powder in purified water with continuous stirring.

Concentration of gelatin = 35-40%

- 2- Vacuum is applied to remove any entrapped air or bubble.
- 3- We can add any Colour, different colours for cap and body for increasing aesthetic appeal and for identification.
- 4- Shells are produced by mechanical dipping of pins or pegs of desired shape and diameter into a reservoir of melted gelatin mixture, maintained at a constant temperature 35-45C to obtain the desired degree of fluidity.
- 5- Then, these pegs overlapped by gelatin are pulled out of gelatin and gelatin is allowed to dry on pegs. Then are removed and shells of required length are obtained by passing hot air through mold.

2- Filling of Capsules:

Formulation, consideration, if the dosage form which is to be incorporated their properties like hygroscopy, flow ability, particle size etc. should be kept in mind.

On Small Scale

In laboratory, a small filling machine is used to fill capsules. Capsules are placed in pin or molds. Cap and body get separated. Powder or any other suitable dosage form is put on the mold containing bodies of capsules. Spread evenly with the help of spatula. Then, caps containing molds is placed on them. Force is applied to close the capsules and fit cap in body.

On Large Scale

Machines developed for industrial use, automatically separate the caps from empty capsules, fill the bodies, scrape off the excess powder, replace the caps, seal the capsules as desired and clean the outside of the filled capsule at upto 1,65,000 capsules per hour.

3- Sealing of Capsules:

For the sealing of capsules, different methods are used like

1. Gelatin banded capsule
2. Heat welded capsule
3. Thermally cold coupled capsules

1- Gelatin Banded Capsules:

Distinctive looking capsules are made by sealing them with a coloured band of gelatin. This band or ribbon act as tape.

2-Heat Welded Capsules

Capsules may be sealed by heat welding process by applying gelatin material in grooves. Heating fuses Capsule cap to the body through the double wall thickness at their juncture.

3-Thermally Coupled Capsules

Another process uses a liquid wetting agent that lowers the melting point in the contact areas of the capsules cap and body and then thermally bonds the two parts using low temperature(40-45C).

4- Imprinting (as an optional step):

A word or company name is imprinted on capsule to make it distinctive.

5- Cleaning of Capsules:

Small amounts of powder may adhere to the outside of capsules. Capsules are dusted by rubbing them with a clean gauze or cloth.

– On large scale, Capsule filling machines are affixed with a clean vacuum.

6- Polishing of Capsules:

After preparation, finishing of capsule is done by salt polishing, pan polishing etc. polishing gives lustrous shine to the capsules.

9.1.3 Packaging of Hard Gelatin Capsules:

1-Bulk Packaging

Plastic bottles contain 500 or larger amount of capsules are packed along with hygroscopic material like silica gel which absorb moisture.

2- Unit Packaging:

- **Blister packaging**

A single capsule as a unit dose is packed in the form of blisters.

- **Strip packaging**

Capsule is placed between two sheets in strip packaging. This packaging is rare.

9.2 Soft Gelatin Capsules:

These capsules are soft, more flexible as contain more moisture content and are used for encapsulation of liquid dosage forms. These are also called soft gel or gel cap.

9.2.11 Composition of Soft Gelatin Capsules:

These are prepared from gelatin to which glycerin or polyhydric alcohol such as sorbitol has been added to render the gelatin elastic or plastic. Soft gelatin capsules which contain more moisture than hard capsules may have a preservative such as methyl or propyl paraben to retard microbial growth.

Examples include digoxin, vitamin E, Demeclocycline HCL etc.

Shape:

They are available in many shapes like oval, round, oblonged, tubular.

Colour:

These may be single colored or two-toned.

Markings:

These may be imprinted with identifying markings.

9.2.2. Types of Soft Gelatin Capsules:

There are two types of soft gelatin capsules;

- Chewable soft gelatin capsules
- Twist off soft gelatin capsules

1- Chewable soft gelatin capsules:

These capsules are orally administered capsules having appreciable taste.

2- Twist Off soft gelatin capsules:

These capsules have one end smaller and other end larger. Narrow end is twisted, throw and remaining is used. E.g. polio drops.

9.2.3 Composition of Gelatin In Soft Gelatin Capsules:

- Mostly type B gelatin is used which is obtained by alkaline treatment of bones.
- Can use combination of both A and B.
- Add plasticizers like sorbitol, glycerol or their combination. Concentration of plasticizer is 20-30%.
- Water content in soft gelatin capsules itself is less 5-8%.
- Different flavours and colours are added. They are mostly of yellow and green in colour for identification purpose.

9.2.4 Manufacturing of Soft Gelatin Capsules:

Manufacturing of soft gelatin capsule mainly contain 2 processes which are

- Plate process
- Rotatory dye process

1- Plate process:

- A warm sheet of plane or coloured gelatin is placed on the mold and the medication containing liquid is evenly poured on it.
- Then a second sheet of gelatin is carefully placed on top of medication and the top plate of the mold is put into place.
- Pressure is then applied to the molds to form, fill and seal the capsule simultaneously.
- The capsules are removed and washed with a solvent harmless to capsules.
- Remaining gelatin is again collected from the spaces between cavities and then reused.

2- Rotatory Dye Process:

- By this method, liquid gelatin flowing from an overhead tank is formed into two continuous ribbon by rotatory dye machine and brought together between twin rotating dyes.
- At the same time, metered filled material is injected between the ribbon precisely at the moment that the dyes form pockets of the gelatin ribbons.
- These pocket are sealed by pressure and heat and then severed from ribbon. Use of ribbon of different colours result in bicolored capsules.

9.2.5 Advantages of Soft Gelatin Capsules:

- Soft gelatin capsules are pharmaceutically elegant and have more aesthetic appeal.
- They are easily swallowed as more slippery on tongue.
- They may be employed to contain liquid, suspension, pasty material, dry powders, preformed tablets.
- Standard gelatin capsules are preferable when it is desirable to seal the medication within the capsule.
- Volatile drug substances, especially susceptible to deterioration in the presence of air may be better suited to a soft capsule.
- Poorly soluble oils can be administered in S.G.C like cod liver oil.
- Low melting point drugs can be incorporated in S.G.C.
- Highly potent drugs can be administered.
- S.G.C are especially important to contain drug solutions or liquid drugs which absorbed and show therapeutic effect readily.

- Dose uniformity is achieved by unit dosing.

9.2.6 Packaging of Soft Gelatin Capsules:

Bulk Packaging:

Capsules are packaged in glass or plastic bottles packets of desiccant material are added to container to prevent absorption of excessive moisture by capsules.

Soft gelatin capsules have greater tendency to soften and adhere to one another. So, these must be stored in cool places, low humidity level and well closed container.

Unit Packaging:

S.G.C can be packaged in the form of blisters for unit dose usage.