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# A DETAILED REVIEW ON CAPSULES

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**Abstract:**

*The drug and the excipients are enclosed in either a soft or hard soluble shell. Generally, thecapsules are the solid preparations. The Shell which is used for closing the drug are made of gelatin or the polymeric substances. The capsules are tasteless, odourless, elegant and easy to swallow. They are either soft capsules or hard capsules where the soft capsules possess a flexibility and plasticized gelatin film while the hard capsule composed of two pieces, the shorter piece called cap and longer piece called body.*

***Keywords****: capsules, soft gelatin capsule, hard gelatin capsule, shell.*

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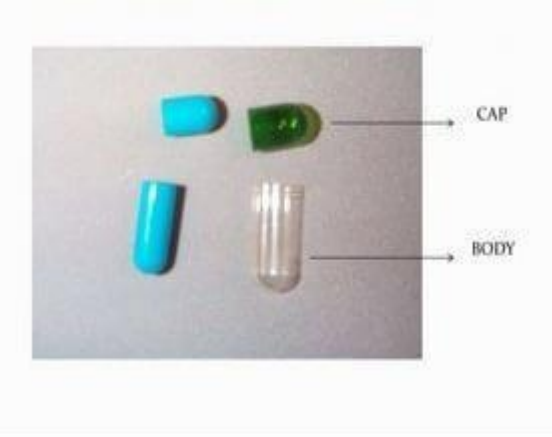
## INTRODUCTION:

Capsules are defined as unit solid dosage form of medicaments available as smallcontainers made up of gelatin enclosing accurately measured drug substances.

Capsula is the Latin word which gives the term capsule which means small container.

Because of the manufacturing process compared to the other dosage forms the capsules are believed as the primary oral dosage form. The medicament is released when the gelatin comes in contact with the water as the gelatin has the disintegrating property.

The capsule shell can be made with the gelatin, denatured gelatin, methyl cellulose, Polyvinyl alcohol (1). Occasionally capsules may be administered rectally andvaginally. The medication can be powder or a liquid or semi solid mass (2).




History:

1830-Capsules were first patented by Joseph Gerard Auguste Dublanc and francois Achillewhich are made from soft gelatin.

1846 - two-piece hard capsules patented by Jules lehuby.

1931 - Aurthur Calton invented a machine that make hard capsules (3).

**Advantages:**

1. The appearance of capsule is neat & elegance.
2. Tasteless, odourless so easy administration.
3. The medication is released rapidly because of the solubility of gelatin at gastric pH. 4.Increases rate of release of the drug.
5. patient compliance.
6. Easily swallowed.
7. Rapid disintegration.
8. Rapid bioavailability.
9. capsules are smooth (4).

**Disadvantages:**

1.Not preferred for efflorescent or deliquescent materials.

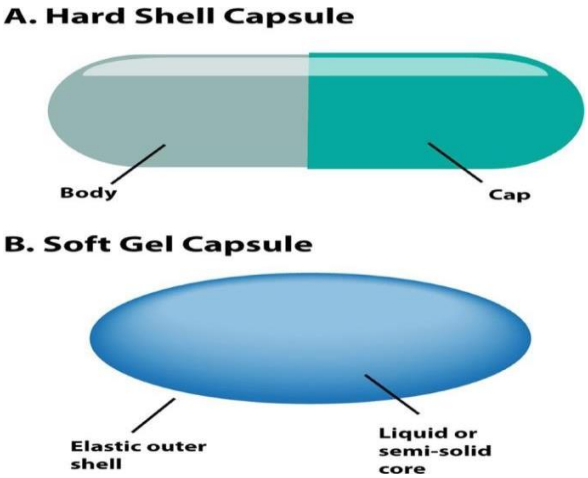
2) Capsules are not suitable for liquids that dissolves gelatin.

3)The rapid release of materials such as very soluble salt like bromides, Iodides should notbe dispensed in capsules (4).

**Types of capsules:**

There are two types of capsules and they are

1. Hard gelatin capsules.
2.soft gelatin capsules.




**Soft gelatin capsules**:

Developed in 19th century to mask unpleasant taste and odor of drug Substances. It hasmany applications for pharmaceutical, health and Cosmetic purposes (5)

A soft gel capsule is one piece containing a liquid, a suspension or semisolid referred toas fill. The rotary die process is involved for the preparation of soft gelatin capsules.

Generally, the soft gelatin capsules are made from gelatin.They are subdivided into two types:

(a) soft gelatin capsules.
(b) Non gelatin soft capsules (6).

The soft gelatin capsules are preferred for the strategic reasons, safety aspects and becauseof the consumer preferences (7).

The components involved in soft gelatin capsules are gelatin, preservative, colorants, andflavors.

Gelatin:

It is the basic component of the soft gelatin capsule. The gelatin is alkali processed whichconstitutes 40%

of the wet molten gel mass.

Plasticizing agent:

They are added to ensure the flexibility. These agents promote the retention or moisture. Eg: glycerol, sorbitol mannitol, polypropylene glycol.
Water:

The water is important in manufacturing process to ensure that capsule is flexible. Itaccounts for 30-40% of the wet gel formulation.

Preservatives:

They are used to prevent the growth of bacteria.

Eg: ethyl hydroxybenzoate, propyl hydroxybenzoate, methyl hydroxybenzoate, potassiumsorbate.

Colorants and opacifier:

The darker color is preferred for the visual appeal and also reduces the penetration of Light for the encapsulation of a photosensitive drug.

Flavoring and sweetening agents:
They are used to improve the palatability.Polymers:
They are used to impart enteric release and to formulate the chewable capsules.Chelating agents:

They are used to prevent chemical degradation of oxidation. Eg: EDTA (ethylene diamine tetrameric acid)(6)(8).

**Hard gelatin capsules**:

It is simple dosage form for oral drug delivery. This type of capsule consists of two pieces

(1) cap, (2) Body.

These capsules are generally cylindrical in shape (9), (10).

They contain only 12-16 % of moisture. The Capsules are filled with dry solids and they are powders, granules, pellets, Tablets (11).

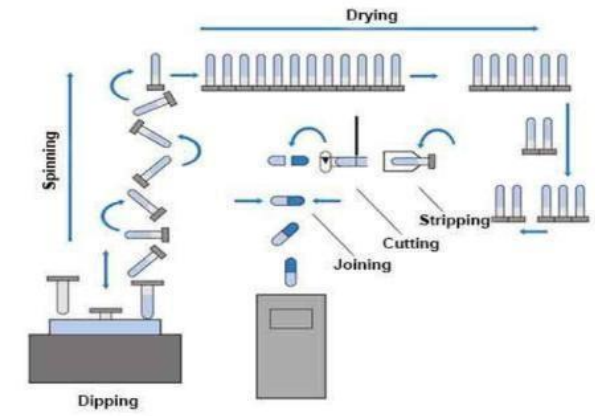
Basic component of hard gelatin capsules:

Gelatin : It is the well-known material for the preparation of hard capsule shells .Thismaterial can be obtained from the skin, white connective tissue, bones of animals.

Plasticizer: They are used to reduce the rigidity of the polymer.Eg: glycerine, polyhydric alcohol.

Colorants, preservatives and opacifying agent, are also used as excipients in the hardgelatin capsules (12), (13).

**Manufacturing of hard gelatin capsules:**




steps involved:

Dipping, Spinning, drying, Stripping, Trimming, and joining, polishing.Dipping:

The stainless-steel pins are dipped into the Solution to form the capsule which includes thecap and the body. The temperature must be maintained at 50°C in a Jacketed dipping pan.

Spinning:
The pins are rotated for the uniform distribution of the gelatin to avoid the formation Ofthe bead at the end of the capsules.
Drying:

It is done to dry the gelatin with the air to form the shell.stripping:

To strip the cap and body portions from the pins.

Trimming & joining:

The cap and body are trimmed with the knives and later they are joined(14),(15).

Filling of hard gelatin capsules: various filling machines are available-

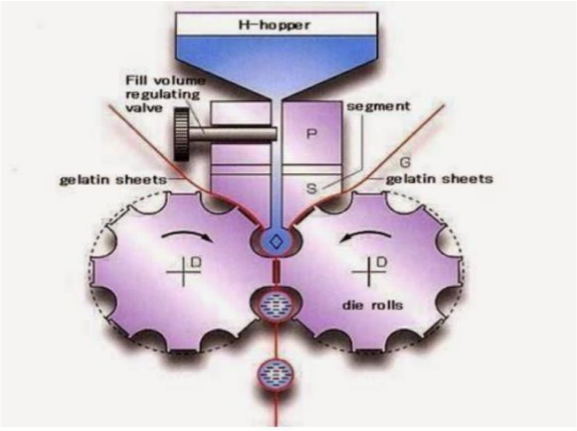
- Eli-lily and co
- Macofar SAS
- Farmatic
- Osaka
- Hofliger

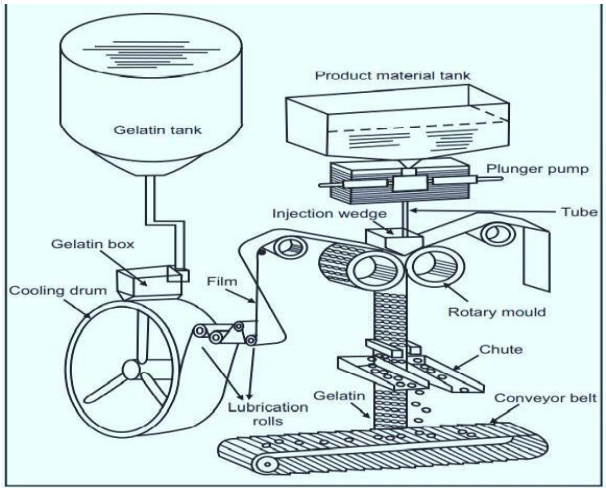
- parke-dare (15), (16).

**Manufacturing of soft gelatin capsule:**

It involves four methods:

1) plate process




2) Accogel machine
3) Rotary die process
4) Bubble method.

Rotary die process:

The gelatin sheets are feed on rolls contain small Orifice hinded up with the die pocket. Thematerial flows with the gravity. The gelatin ribbons are fed with the paste between the rollers and the sealing is done by the mechanical pressure (17).

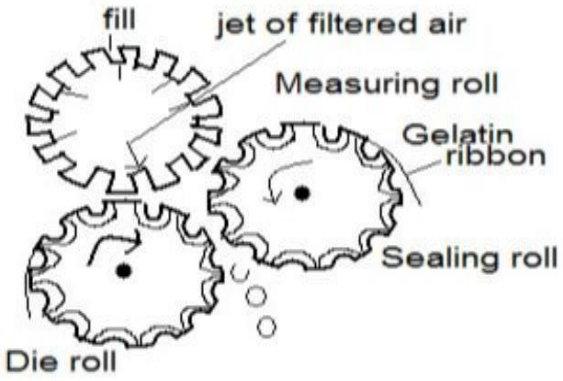
Plate process:
The plate contains the numerous die pockets where the gelatin sheet is placed. The sheet isdrawn into the die pockets with the help of the vacuum. Then the pockets are filled with the liquid or the paste. The another Sheet is used for placing them on the filled pockets and sandwiched under a die press (18).

Accogel machine:

It Involves mainly those parts -

1) Measuring you
2) Die roll
3) Sealing roll

The gelatin is transferred into the gelatin linked pocket with the help of measuring roll anddie roll. Then the Second gelatin Sheet is applied to form the other half of the capsule. pressure between the die & Sealing roll cuts out the capsule (17).




Bubble method:

The molten gelatin is discharged into the outer annulus and liquid content from the tube. Then the liquid discharged into the chilled-oil of column as droplets from the concentric tube (19).

**Evaluation test for capsules:**

**1)** content uniformity test:
The amount of active ingredient should be within the range of 85% to 115% of the labelamount for 9 of 10 capsules with no unit outside the range of 70% to 125% of label amount (20).

**2)** weight variation test:
The average weight of the 20 tablets are calculated after weighing each tablet. If the weight of the individual capsule falls within 90-110 %of the average weight then the test is passed (21).

**3)** Disintegration time test for capsules:
It is done to ensure that the drug Substance is fully


| Size | Volume in ml | Size in mm |
|---|---|---|
| 000 | 1.37 | 26.3 |
| 00 | 0.95 | 23.7 |
| 0 | 0.68 | 21.8 |
| 1 | 0.50 | 19.2 |
| 2 | 0.37 | 18.3 |
| 3 | 0.30 | 15.3 |
| 4 | 0.21 | 14.7 |
| 5 | 0.15 | 11.9 |

available for dissolution and absorption from the gastrointestinal tract. The Capsules taken in the basket rack assembly and lowered for 30 minutes into a thermostatically controlled bath of fluid at 37+/-2degrees celsius (5).

**4)** Shelf-life test:
test done after the storage at predetermined conditions. This test helps in verifying theshelf life & stability of the drug (22).

**5)** Dissolution test:
Take 1000ml of water at 36.5° into the vessel and add specified number of Capsules in basket and adjust the speed to 100rpm.Withdraw the required volume for every 10 minutes time interval. The Sample passes the test if the amount of Active ingredients in thesolution is not less than 70% of the standard amount (23).

**6)** moisture permeation test:
The color change indicates the preserve of the moisture and the drug also gains the weight by absorbing the moisture (24).

**Storage:**
Hard gelatin capsules:

They should be stored at 24° to 28 degrees celsius. At high humidity they absorb moistureand lose its shape and at low humidity, they loss water and become brittle.

Soft gelatin Capsules:

Humidity does not exceed 45%RH at 21-24degrees celsius (25).

**Stability:**
It is done to determine the shelf life of capsule and to maintain the physical, chemical, microbiological, therapeutic, and toxicological identification right from the date of formulation and packaging until its therapeutic action (25).

**Sizes of the capsules:**

- The largest size of the capsule is No:000.
- The Smallest size of the capsule is No:5.
- The standard shape of capsule is traditional, Symmetrical and bullet shape(26).

**FUTURE PERSPECTIVE:**
Due to the rapid advances in capsule dosage form the hard gelatin capsules are morepreferred.

- There will be more growth on the plant- based capsules as the people look for the quality & Lifestyle fit.
- As the rapid sealing technology is available, the capsules will be more preferred.
- Capsule manufacturers will continue to improve the materials, processes and relatedtechnologies to this versatile dosage form.

## CONCLUSION:

Capsules are solid preparations in which drug substance and / or excipients are enclosed ineither soft or hard soluble shell.

Depending upon the composition of the Capsule shell, the capsules are classified as hard or soft capsule. Capsules are filled with a range of formulation types like dry powders,semi solids, nonaqueous liquids and other dosage forms.

## REFERENCES:

1) Meinzer ,A. Studies on oxygen permeability of soft gelatin capsules. PhD Thesis, Freiburg Br.Germany 1988.
2) Fridrun Podczeck and Brian E jones. The history. of the medicinal capsule in pharmaceutical capsules ;2nd ed. 2004:1.
3) USP 31-NF 26. Rockville, MD: US Pharmacopeial Conventions ;2001:1.
4) Stevens ,p.v (1992). "Unknown". food Australia 44 (7) :320-324. http://www.gelatin.co.za/gltn1.html.
5) Ghosh,Tand Jasti , B. Theory and practice of contemporary pharmaceutics.USA: CRC Press LLC, 2005.
6) Dr. Bhawana Bhatt, S.s Agrawal pharmaceutical Technology capsules available from:http://nsdl.

Niscair.res.in/ bitstream.
7) Gibson, M pharmaceutical preformulation and formulation: A practical Guide from candidate Drug selection to commercial Dosage form. New York: Taylor & Francis Group,2009.
8) Hoag,s Capsules Dosage form :formulation and Manufacturing considerations. In Y. Qui,y.chen, G.Zhang, L. Yu, and R. Mantri (Eds),Developing solid Oral Dosage forms- pharmaceutical theory and practice (2nd Ed) (pp. 723-747), UK:Elsevier Inc, 2017.
9) http://in Wikipedia .org/ wiki/Gelatin.
10) http://www.rjengineering.com/reach.html.
11) Lippincott Williams and Wilkins.. "Oralsolid dosage form ”in Remington-The Science and practice of pharmacy ,21th ed. volume-1:921.
12) Shayne, c. pharmaceutical Manufacturing Handbook: production and processes. NewJersy :John Wiley & Sons, Inc. 2008.
13)Ofoefule, s. Textbook of pharmaceutical technology and Industrial pharmacy Nigeria: Samakin(Nig)Enterprise,2002.
14) kontny MJ, Mulski CA. Gelatin capsule brittleness as a function of relative humidity at room temperature. Int J. Pharm. 1989:54:79-85.
15) Gabriele Reich, formulation and physical properties of soft capsules available from: http://www.pharmpress.com.
16) Overholt, S.M. Chewable soft capsules. us patent 6258 380/2001.
17) Murthy ks, Reisch RG Fawzi MB. Dissolution test conditions of hard-Shell products. Part2 . The effect of dissolution test conditions on inVitro drug release. pharm .Technol.1989; 13:53-58.
18) Murthy kS, Enders NA, Fawzi MB. Dissolution Stability of hard shell product. part I. Theeffect of exaggerated storage conditions pharm Technol. 1989;13:72-84.
19) Draper, P.R., Tanner, K. E., Getz ,J.J., Burnett, S. and Youngblood ,E. film forming compositions comprising modified scratches and iota-Carrageenam and methods formanufacturing soft capsules using same. International patent Application Woo 103 677.1999.
20) Ongura,T., Furuya, Y. and Matsuura,s. Hpmc capsules-An alternative to gelatin. Pharm. Technol. Eur., 1998;10 (11): 32,34,36,40,42.
21) Moawia M. Al-Tabakha, Hpmc capsules :Current status and future prospects, Drug.
22)Mahato, R. and Narang, A .pharmaceutical Dosage forms and Drug delivery (3rd ed.). New York: Taylor & Frances Group, 2018.
23) N. Hoshi et al.,pharma Tech. Japan, 2003; 19(1):17-30.
24) Brown, M.D. Improvements in or relating to encapsulation. International patent Application WO 9735 537.1996.
25) N. Hoshi, "Abstracts of 2nd Symposium on formulation Technology" (Tokyo, Japan, 2004) BI-B12.
26) Begum et al., World J pharm Sci 2018, 6(8):98-105.