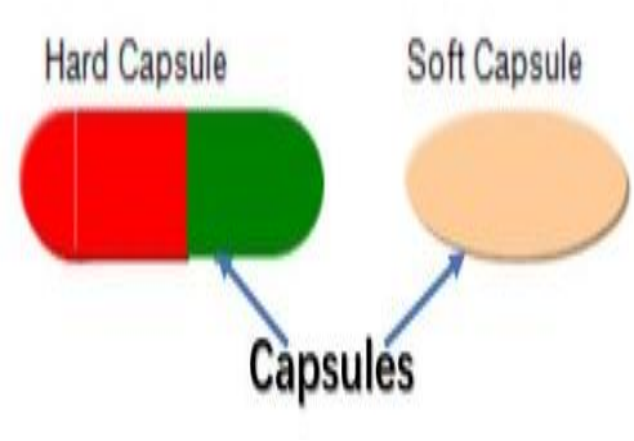
CAPSULE

Capsules are solid dosage forms in which the drug substance is enclosed in a water soluble shell of or an envelope. A capsule shell is made from gelatin.



TYPES OF CAPSULES:

1) Hard Gelatin Capsules

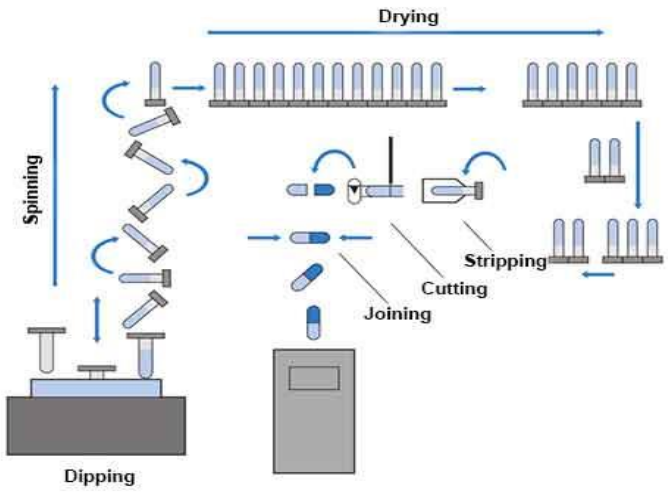
2) Soft Gelatin Capsule

Hard Gelatin Capsule	Soft Gelatin Capsule
1. Shell consists of two parts: a) Body b) Cap	1. Soft gelatin capsule shell becomes a single unit after sealing the two halves of the capsules.
2. Contents: a) Medicaments or mixture of medicaments. b) Coloring agent c) Plasticizer	2. Contents: a) Liquids or solids dissolved or dispersed in suitable excipients to give a paste like consistency. b) Plasticizer c) Gelatin d) Preservative

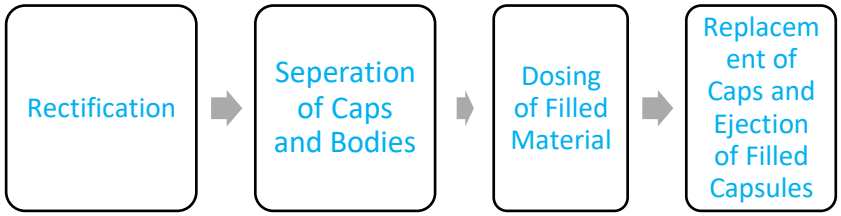
Size of Capsule:

Capsule Size	Water Volume (ml)	Approximate Capacity in (mg)
000 (Largest)	1.37	950
00	0.95	650
0	0.68	450
1	0.50	300
2	0.37	250
3	0.30	200
4	0.21	150
5 (Smallest)	0.13	100

Production of Hard Gelatin Capsule:



Filling of Hard Gelatin Capsules:



Finishing of Hard Gelatin Capsules:

1. Pan Polishing
2. Cloth Dusting
3. Brushing

Special Techniques of Formulation of Hard Gelatin Capsules:

1. Imprinting
2. Different types of coatings like salol, cellulose acetate phthalate is employed to modify solubility characteristics.
3. Incompatible materials are separated through two-phase fill in the capsule.

In process and Quality Control Tests:

1) Unique Identification Tests

2) Size and Shape

3) Content Uniformity Test:

30 Capsules are taken. Out of 30, 10 capsules are assayed.

Test is pass if 9 out of 10 are within potency range of 85-115% and 10^{th} is not outside 75-125%

If more than 1 but less than 3 of the first 10 capsules fall outside 85-115% then remaining 20 capsules are assayed.

Test is pass if, out of 30 capsules, all lie within the potency range 75-125% and not less than 27 out of 30 are within 85-115% range

4) Weight Variation Test:

20 Capsules are individually weighed and average weight is calculated

Test is passed if none of individual weight is less than 90% or more than 110% of average weight.

If test is failed, then individual net weights are determined and average is calculated. Difference between each individual net content and average is determined.

The test is pass if 1) not more than 2 of the individual difference greater than 10% of average

2) In no case, any difference is greater than 25%

If more than 2 but less than 6 capsules net weight deviate by more than 10% but less than 25% then net content of additional 40 capsules is determined

The average is calculated of total 60 capsules. The test is passed if 1) Difference does not exceed 10% of the average in more than 6 of the 60 capsules2) If in no case any difference exceeds 25%

5) Disintegration Test

6) Dissolution Test: Basket type or paddle type dissolution apparatus is used.

Stage	Number of dosage of units tested	Acceptance criteria
S1	6	No dosage unit is less than Q+5%, if fails then S2 is performed
S2	Another 6 (i.e. 12)	Acceptable if average of 12 tablets is greater than or equal to Q and no unit is less than Q-15%. If fails then S3 is performed
S3	Another 12 (i.e.24)	Acceptable if, average of all24 capsules is greater than or equal to Q and not more than 2 capsules are less than Q-15%

SOFT GELATIN CAPSULE:

Nature of shell:

a) Bloom or Gel Strength

1) The bloom or gel strength of gelatin is a measure of the cohesive strength of the cross - linking between gelatin molecules and is proportional to the molecular weight of the gelatin.

2) Bloom is determined by measuring the weight in grams required to move a plastic plunger that is 0.5 inches in diameter into a 6 2 /3% gelatin gel that has been held at 10°C temperature for 17 hours.

3) Bloom may vary with the requirements of the individual custom manufacturer but ranges from 150-250gm.

b) Viscosity:

1) Viscosity of gelatin, determined on a 6 2 /3% concentration of gelatin in water at 60°C temperature

2) The viscosity for gelatin can range from 25-45millipoise

Capsule Content:

The maximum capsule size and shape for convenient oral use in humans is the 20 minim oblong, the 16 minim oval, or the 9 minim round.

Size of Capsule:

Soft gelatin capsules are available in oblong, spherical, elliptical, and other shapes. Spherical or oval capsules are also known as pearls pr globules.

They are also available in different size ranges from 0.1 to 30 ml.

Different shapes and capacities of soft gelatin capsules are:

Spherical : 0.05-5ml

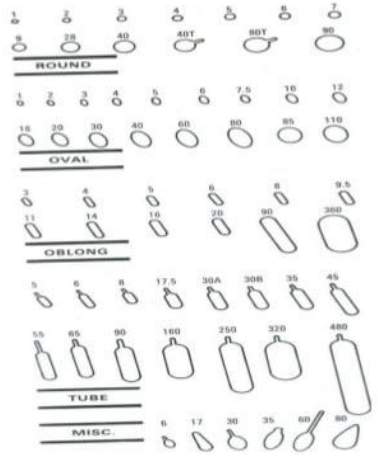
Ovoid : 0.05-7ml

Cylindrical : 0.15-25ml

Tubes :0.5-0ml

SHAPE OF CAPSULE

The shape of soft gelatin capsule are round, oval, oblong, tube.



Importance of Base Adsorption (BA):

1) Base adsorption is expressed as the number of grams of liquid base required to produce a capsulatable mixture when mixed with one gram of solid.

Weight of Base = Base Adsorption

Weight of solid

2) Importance of Minim per Gram Factor (M/g) :

The base adsorption is used to determine the minim per gram factor (M/g) of the solid(s). The minim per gram factor is the volume in minims that is occupied by one gram (S) of the solid plus the weight of liquid base (BA) required for making a capsulatable mixture.

Manufacturing defects:

1) Deliquescent or Hygroscopic Powders

2) Segregation and Homogeneity

3) Incompatibility

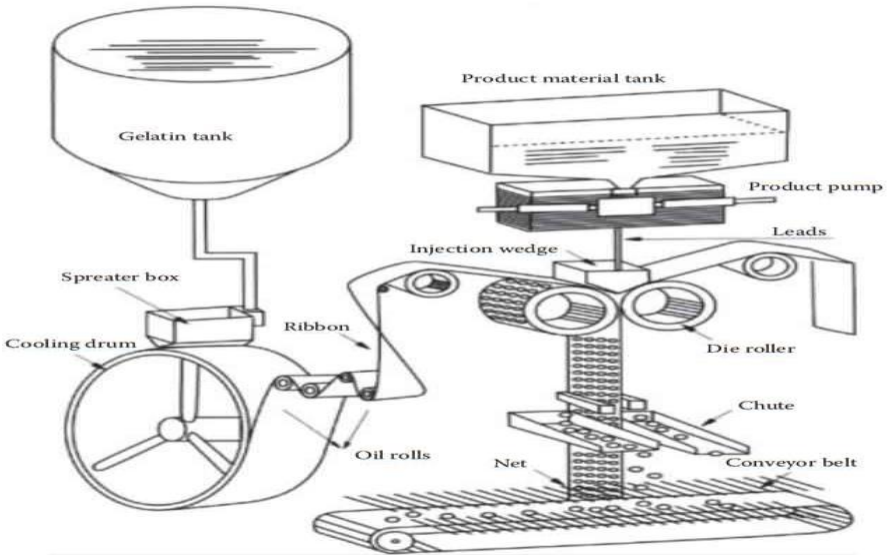
Production:

Rotary die machine is used

1) Automatic machine

2) It can produce 25000-30000 capsules per hour

3) The gelatin sheets come between the rollers, the material to be filled is injected through a metering device



Rotary Die Machine Diagram

Gelatin Melting Tank:

Encapsulation: This process brings the gelatin shell and the fill material together to form soft gel capsules. This process is carried out in closed environment called clean rooms

Drying: The purpose of this step is to decrease the moisture content and create hard and durable finished soft gel capsules.

Inspection: Due to the air pockets in the gelatin and filled material soft gel capsules may vary in size and need to inspect visually.

Polishing: Before packaging is to clean and polished soft gel capsule to remove any mineral oil or glycerin that capsule may have no their exterior skin.

Packaging: Any finished soft gel product should be stored in an environment with temperature around 20 to 24 degree Celsius and 35% relative humidity.

In Process and Quality Control Tests:

1. Permeability and Sealing
2. Weight Variation test
3. Content Uniformity Test

Packing, Storage and Stability Testing of Soft Gelatin Capsules:

Dispensing of capsules should be carried out in tightly closed containers made up of glass or plastic. The containers should be protected from dust and extreme conditions of humidity and temperature.

Moisture contents : 10 to 15 %

Relative humidity : 40 to 60 %

Storage : At cool place, at temperature not beyond 30 degree Celsius.

Applications:

1) Ophthalmic soft gelatin capsules
2) Chewable soft gelatin capsules
3) Controlled release soft gelatin capsules
4) Enteric coated soft gelatin capsules
5) Gelatin free soft gelatin capsules
6) Suckable soft gelatin capsules
7) Twist off soft gelatin capsules

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Academic Year	:	2021-22
Reference	:	1) Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy 2) Dispensing Pharmacy by R. M. Mehta