SOFT GELATIN CAPSULE

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Definition:-

Soft gelatin capsules are one piece, hermetically sealed, soft gelatin shells containing a liquid, a suspension, or a semisolid.

Soft gelatin is mainly composed of:

Gelatin, plasticizers, and water in addition to preservative, colouring and opacifying agents, flavoring agents and sugars.

APPLICATIONS OF SOFT GELATIN CAPSULE

1. As an oral dosage form for human or veterinary use.
2. As a suppository dosage form for rectal (pediatric and geriatric) or vaginal route.
3. As a specialty package in tube form, for human or veterinary single dose application of topical, ophthalmic and otic preparations and rectal ointments.

SHAPE OF CAPSULE

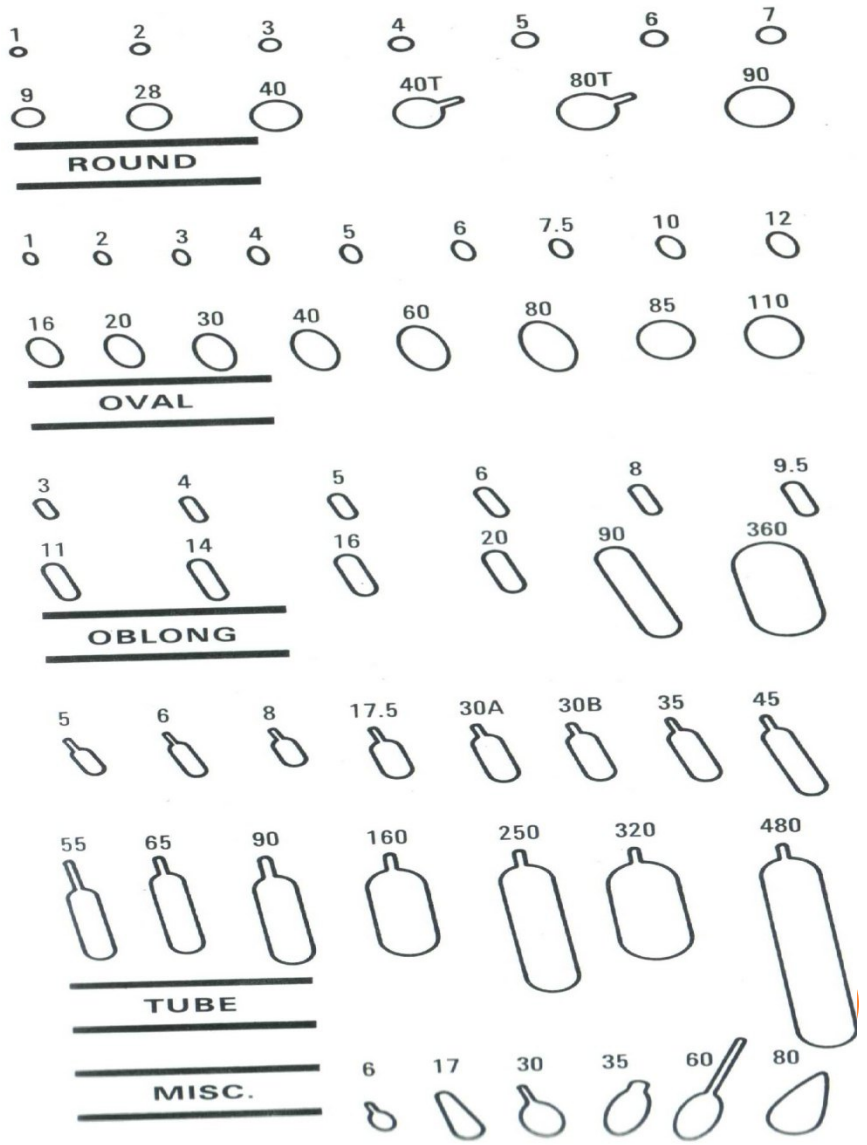
The shape of soft gelatin capsule are round, oval, oblong, tube.

Maximum capsule size and shape convenient for oral human use is:

20 minim oblong

16 minim oval

9 minim round



MANUFACTURE OF SOFT GELATIN CAPSULES

Is manufactured by four methods

- Plate process.
- Rotary die process.
- Reciprocating die (developed process for rotary die).
- Accogel machine (unique equipment that accurately fills powdered dry solids into S.G.C.).

Plate process: (oldest process)

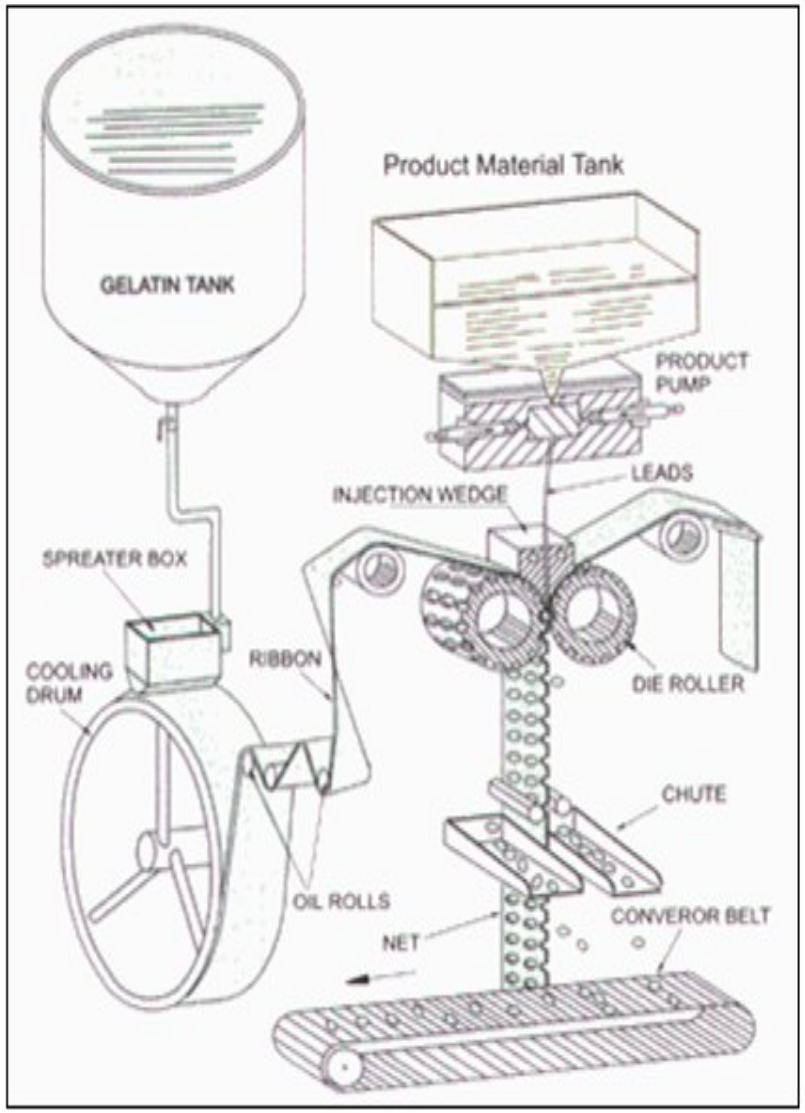
- Gelatin sheet is placed over a die plate containing numerous die pockets,
- Application of vacuum to draw the sheet in to the die pockets,
- Fill the pockets with liquid or paste,
- Place another gelatin sheet over the filled pockets, and
- Sandwich under a die press where the capsules are formed and cut out.

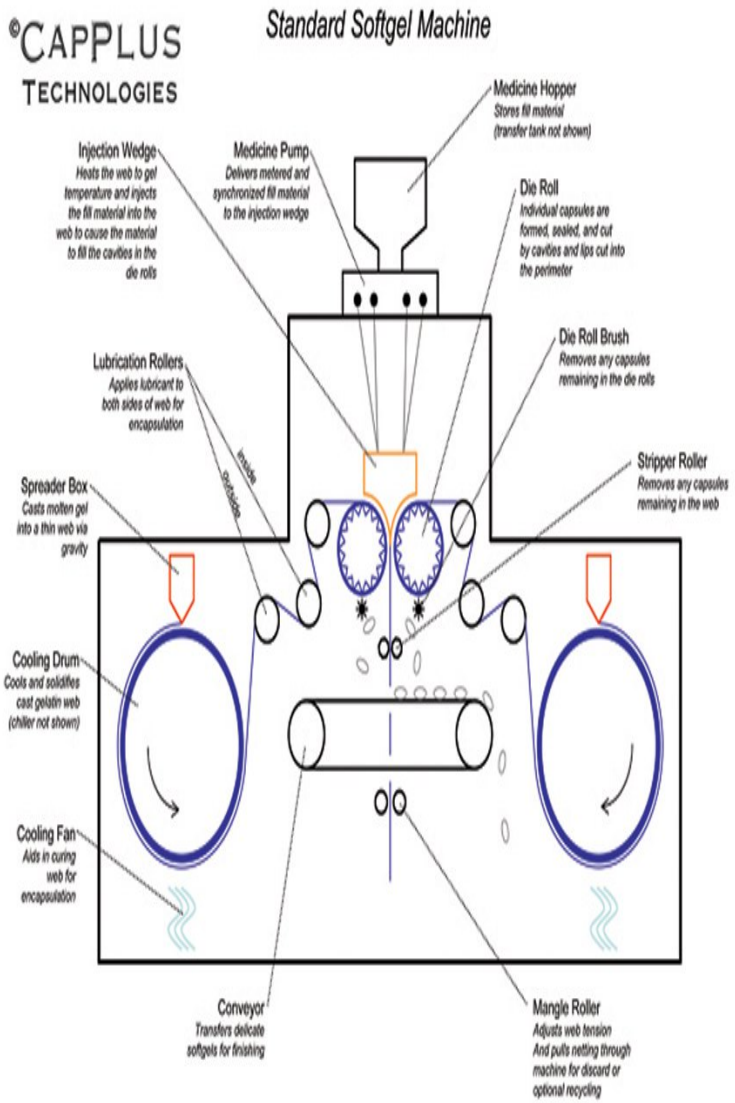
Rotary die process:

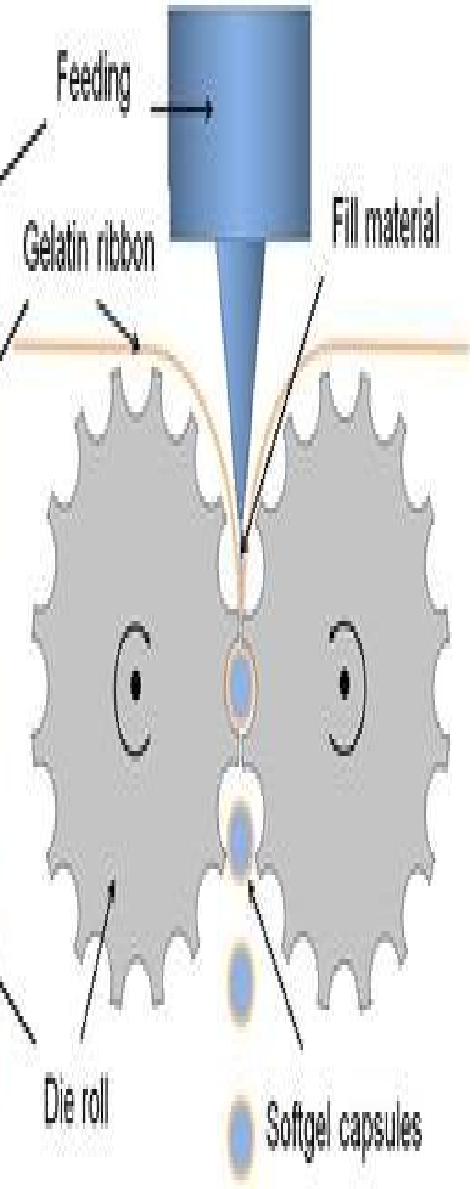
The material to be encapsulated flows by gravity. Two plasticized gelatin ribbons are continuously and simultaneously fed with the liquid or paste fill between the rollers of the rotary die mechanism where the capsule are simultaneously filled, shaped, hermetically sealed and cut from the gelatin ribbon.

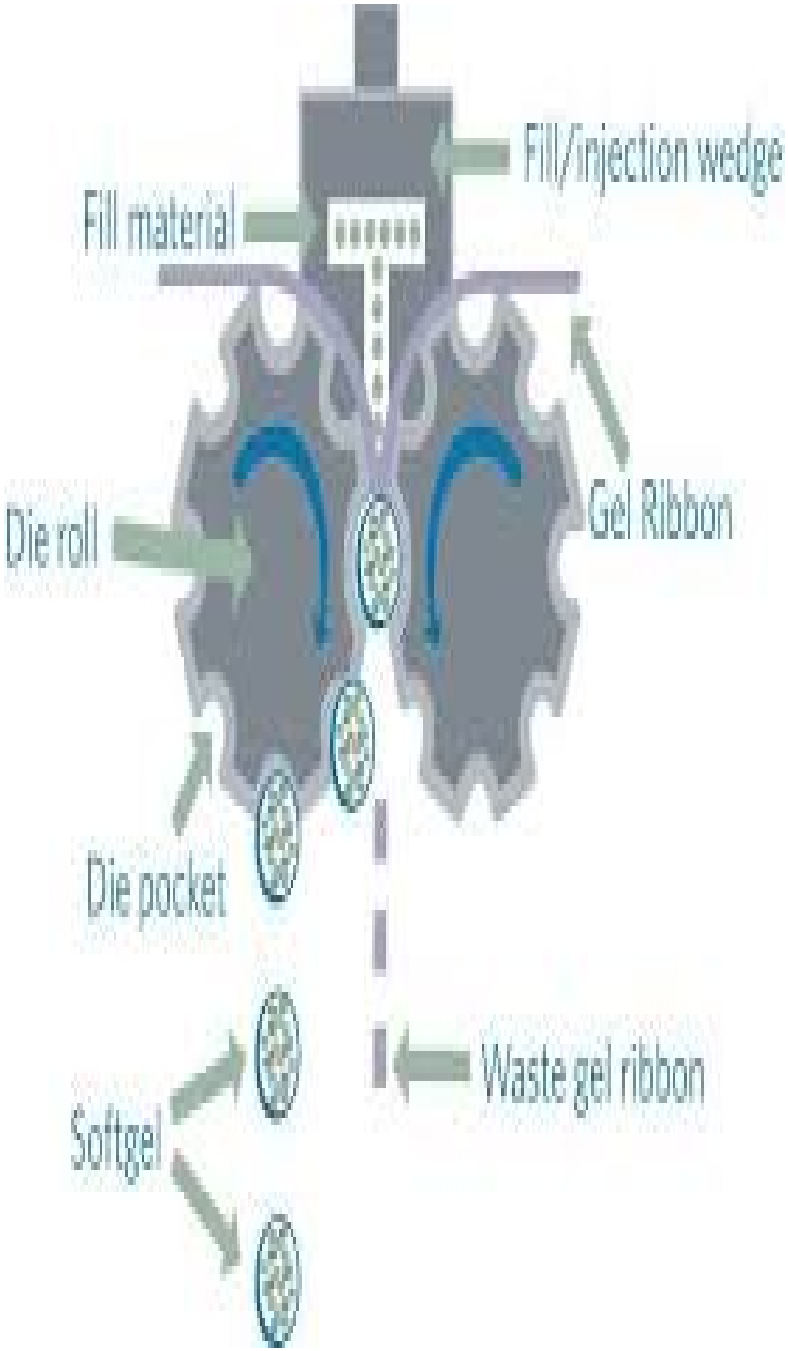
The sealing of the capsule is achieved by mechanical pressure on the die rolls and the heating(37-40°C) of the ribbons by the wedge.

The rotary die process






Feeding
Gelatin ribbon
Fill material
Die roll
Softgel capsules


Fill/injection wedge
Fill material
Gel Ribbon
Die roll
Die pocket
Waste gel ribbon
Softgel

Nature of capsule shell

IMPORTANT SPECIFICATIONS OF GELATIN

Bloom or gel strength: It is a measure of cohesive strength of cross-linkage that occurs between molecules and is proportional to the molecular weight of gelatin.

Bloom is determined by measuring the weight in grams required to move a plastic plunger of 0.5 inches in diameter, 4mm to depress the surface of 6.67 % gelatin gel that has held at 10°C for 17-18hrs without breaking.

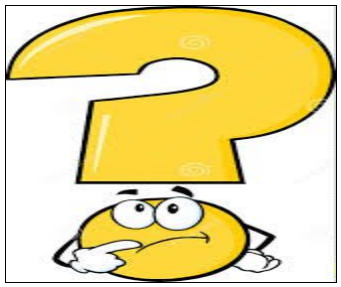
The unit of bloom is grams and it is between 150-250g.

Viscosity: Is determined on a 6.67% concentration of gelatin in water at 60°C and it is a measure of the molecular chain length.

Standard gelatin used: viscosity 25-45 millipoise with high Bloom (180-250g) gelatin used for capsulation of hygroscopic vehicles or solids.

Iron content: Iron is always present in the raw gelatin, and its concentration usually depends on the iron content of the large quantities of water used in its

Amount of iron should not exceed 15ppm. Why??? (HW)



Plasticizer and Gelatin ratio

In soft gelatin capsule the amount of plasticizers (glycerin) used is more.

In soft gelatin capsule the plasticizer and gelatin ratio is:

0.8 : 1

In hard gelatin capsule the plasticizer and gelatin ratio is:

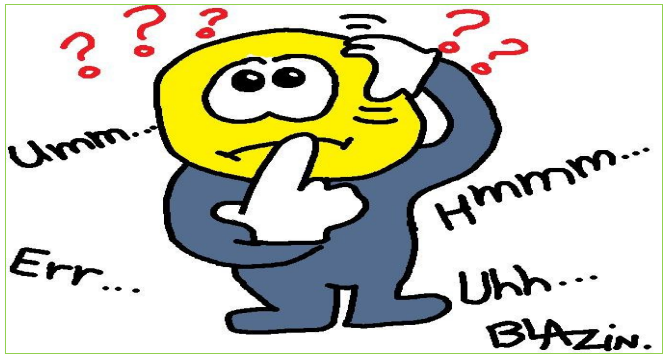
0.4 : 1

Typical Shell "Hardness" Ratios and Their Uses

Hardness	*Ratio Dry Glycerin/ Dry Gelatin*	*Usage*
Hard	0.4/1	Oral, oil-based, or shell-softening products and those destined primarily for hot, humid areas.
Medium	0.6/1	Oral, tube, vaginal oil-based, water-miscible-based, or shell-hardening products and those destined primarily for temperate areas.
Soft	0.8/1	Tube, vaginal, water-miscible-based or shell-hardening products and those destined primarily for cold, dry areas.

TABLE 13-3. *Additional Components of the Gelatin Mass*

Ingredient	*Concentration*	*Purpose*
Category I		
Methylparaben, 4 parts; Propylparaben, 1 part	0.2%	Preservative
FD&C and D&C water-soluble dyes, certified lakes, pigments, and vegetable colors, alone or in combination	q.s.	Colorants
Titanium dioxide	0.2 to 1.2%	Opacifier
Ethyl vanillin	0.1%	Flavoring for odor and taste
Essential oils	to 2%	Flavoring for odor and taste
Category II		
Sugar (sucrose)	to 5%	To produce chewable shell and taste
Fumaric acid	to 1%	Aids solubility; reduces aldehydic tanning of gelatin



Choosing the color added for gelatin mixture depend on what ??? (HW)

The nature of capsule content

√ The content of soft gelatin capsule is a liquid, or a combination of miscible liquids, a solution of solid in a liquid or suspension of solid in liquid.

√ Liquids are both water-miscible and volatile can not be included as a major constituent of capsule content since ……(H.W)

√ Gelatin plasticizers such as glycerin and propylene glycol can not be major constituents of the capsule content, owing to their softening effect on the gelatin shell, which thereby makes the capsule more susceptible to effects of heat and humidity.

√ As a minor constituents (up to 5% of cap. contents) water and alcohol can be used as cosolvent.

√ Up to 10% glycerin/ PG can be used as cosolvent.

√ Also, preparations for encapsulation should have a pH between 2.5 and 7.5, since preparations that are more acidic can cause hydrolysis and leakage of the gelatin shell. and preparations that are more alkaline can tan the gelatin and thus affect solubility of the shell.

√ The capsulation of water immiscible liquids (vegetable oils and mineral oils) is the simplest form of soft gelatin capsulation and usually requires little or no formulation.

√ Except for accogel process, solids are filled into soft capsules in the form of either solution or suspension.

√ The preparation of a solution of a solid medicament should be the first goal; usually the solution is easily capsulated and exhibit better uniformity, stability and biopharmaceutical properties than suspension.

√ For oral products, the medicament should have sufficient solubility in the solvent system so that the necessary dose is contained in a maximum fill volume of 16 to 20 minims (1 to 1.25 ml).

√ Solids are not soluble in the solvent system are capsulated as suspension.

√ The choice of suspension medium are directed toward producing the smallest size capsule .

In the formulation of suspensions for soft gelatin encapsulation, certain basic information must be developed to determine the minimum capsule size.

Labratory tool for this purpose is:

√ Base adsorption (of solids to be suspended): is expressed as number of grams of liquid base (insert liquid or vehicle) or minimum quantity of base required to produce a capsulatable mixture when mixed with one gram of solid(s).

√ The base adsorption of solid is influenced by :

- The solid particle size and shape
- Its physical state (fibrous, amorphous or crystalline)
- Its density, moisture content, oleophilic or hydrophilic nature.

- $\frac{\text{weight of base}}{\text{weight of solid}}$ = Base adsorption (unit less)
- The base adsorption is used to determine the " minim per gram " factor (M/g) of the solids .
- The minim per gram factor is (the volume in minims that is occupied by one gram of the solid plus the weight of liquid base(BA) required to make a capsulatable mixture). Or volume of mixture in minim required for solid drug to produce a mixture which can be capsulated.

- Example of liquid base is vegtable oil, PEG 400, Polysorbate 80, Glyceryl monooleate.

- The minim per gram factor is calculated by dividing the weight of base plus the gram of solid(BA+S) by the weight of mixture(W) per cubic centimeter or 16.23 minims (V)

  - $\frac{(BA+S)}{D(w/v)} = \frac{(BA+S)*V}{W} = \mathrm{M/g}$

  - The lower the base adsorption of the solid and the higher the density of the mixture, the smaller the capsule will be.


Thank You.