

INDUSTRIAL PHARMACY-I**UNIT III-CAPSULES****CLASS:21****TOPIC Soft gelatin capsules: Nature of shell and capsule content, size of capsules****SOFT GELATIN CAPSULES****Advantages of soft gelatin capsules:**

- (i) Soft gelatin capsules are useful when it is desirable to seal the medication within the capsule.
- (ii) The capsules are especially important to contain liquid drugs or drug solutions.
- (iii) Also, volatile drug substances or drug materials especially susceptible to deterioration in the presence of air may be better suited to a soft gelatin capsule than hard gelatin capsules.
- (iv) Soft gelatin capsules are elegant and are easily swallowed by the patients.

Capsule sizes and shapes

Shape	Diagram	Size range (number represents the nominal capacity in minims (1 cc = 16.23 minim))
Round		1,2,3,4,5,6,7,9,28,40,90, 40T,80T
Oval		1,2,3,4,5,6,7.5,10,.12,16,20,30,40,60,80,85,110.

Oblong		3,4,5,6,8,9,5,11,14,16,20,90,360
Tube		55,65,90,160,250,320,480

MATERIALS:

The capsule shell is basically composed of gelatin, a plasticizer and water. It may contain additional ingredients such as preservatives, coloring and opacifying agents, flavors, sugars, acids and medicaments to achieve desired effects.

GELATIN

The gelatin should be of USP grade and it should have some additional specifications, namely, bloom strength, viscosity and iron content of the gelatin used.

Bloom or gel strength

It is a measure of the cohesive strength of the cross-linking that occurs between gelatin molecules and is proportional to the molecular weight of the gelatin.

Determination

6 2/3 % gelatin gel kept at 100C for 17 hours A plastic plunger having diameter 0.5 inch.

Bloom strength = the weight (in gram) required to move the plastic plunger in the gelatin mass upto 4 mm.

□ Normally for soft-gelatin capsules the bloom strength of gelatin required ranges from 150 to 250 g.

In general with all the other factors being equal, the higher the Bloom strength of the gelatin used, the more physically stable is the capsule shell.

□ Cost is, in general, proportional to Bloom strength; hence, higher

Bloom strength gelatins are only used when necessary to improve the physical stability of the product or large capsules (over 50 minims).

Viscosity of gelatin

Viscosity of a 6 2/3 % gelatin in water solution at 60°C is a measure of the molecular chain length and determines the manufacturing characteristics of the gelatin film.

General range of viscosity 25 to 45 millipoise, it may be within narrow range 38 ± 2 millipoise.

Iron content

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

Limit: Gelatin used for soft gelatin capsules should not contain more than 15 ppm of iron.

Disadvantages:

- (i) Iron may react with the certified dyes.
- (ii) It may react with organic compounds to produce color (e.g. with phenolic compounds).

PLASTICISERS

Very few plasticisers are used for soft gelatin capsules

- (i) Glycerin USP
- (ii) Sorbitol USP or

(iii) a combination of glycerin and sorbitol

The ration by weight of dry plasticizer: dry gelatin determines the 'hardness' of the gelatin shell.

Typical shell hardness and their uses:

Hardness	Ratio of 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-base, water-miscible-base, or shellhardening products and those destined for temperate areas (hot & humid areas)
Soft	0.8 / 1	Tube, vaginal Water-miscible base or shell hardening products and those destined primarily for cold, dry areas.

Additional components of the gelatin mass

Ingredients	Concentration	Purpose
<i>Category-I</i>		

Methyl paraben		Preservative
Propyl paraben (4 : 1)	0.2 %	
FD&C and D&C water-soluble dyes, certified lakes, pigments, vegetable colours	q.s.	Colorants
Titanium di-oxide	0.2 to 1.2 %	Opacifier
Ethyl vanillin	0.1 %	Flavor
Essential oils	2 %	Flavor
<i>Category-II</i>		
Sugar (sucrose)	to 5 %	To produce chewable shell and taste Aids solubility
Fumaric acid	to 1 %	reduces aldehydic tanning of gelatin

NATURE OF THE CAPSULE CONTENT

Soft gelatin capsules can be used to dispense a variety of liquids,

Solids,

Combination of miscible liquids,

Suspension of solids in liquids.

Selection of capsule size

The maximum capsules size and shape for convenient oral use in humans is the

20 minims oblong,

16 minims oval or

9 minims round

Types of liquids for encapsulation in soft gelatin capsules

1. Water, ethanol, emulsion -these are water miscible or volatile components and they cannot be included as major constituents of capsule since they can migrate into the hydrophilic gelatin shell and volatile from the surface.
2. Gelatin plasticizers like glycerin, propylene glycol cannot be major constituents of capsules owing to their softening effect on the gelatin shell.
3. Upto 10% glycerin and / or propylene glycol can be used as co-solvents with PEG or other liquids that have a shell-hardening effect when capsulated alone.

Most widely used liquids for human consumptions are

- Oil active ingredients e.g. clofibrate
- Vegetable oils e.g. soybean oil
- Mineral oil, non-ionic surfactants e.g. polysorbate 80 and PEG (400 and 600) either alone or in combination
- Fish oils in vitamin capsules.

Other conditions for manufacturing soft gelatin capsules

1. The suspension products must be homogeneous, air free and preferably should flow by gravity at roomtemperature but not a temperature above 350C because the sealing temperature of gelatin films is usually 37to 400C.
2. pH should be in between 2.5 and 7.5, since preparations that are more acidic can cause hydrolysis andleakage of the gelatin shell, and preparations those are more alkaline can tan the gelatin and thus affect thesolubility of the shell.