

PHARMACEUTICS (CAPSULE)

Capsules

Disadvantage:- ♦ Capsule should not be used for highly effluorescent or deliquescent material

- ♦ Effluorescent materials make capsule shell soften.
- ♦ While deliquescent materials make capsule shell upto brittleness
- ♦ Potassium Chloride, potassium Bromide and ammonium chloride not be used in capsule form because they irritate stomach

Capsule shell

Gelatin - Animal collagen

Type A- Acid treated

Iso electric point PH 9

Type B- Alkali treated

∨ Iso electric point 4.7

Green (Fresh) are used

- ♦ Empty Capsule should have Moisture content 12-15 %

Less 10% - Brittle

More than 16% - Size problem

CAPSULE NUMBER AND ITS APPROXIMATE CAPACITY

(Capsule Size)

Capsule Number	Approximate Capacity in mg (Aspirin)
000	950
00	650
0	450
1	300
2	250
3	200
4	150
5 (DCO Raj. Exam-2012)	100

♦ Largest size 000

♦ Smallest size 5

Roto weigh - Capsule weighing machine

Rotosort - Sorting of capsule

Rotofil → Capsule filling (fill pellet) machine

Weight Variation	% Limit
Less than 300 mg	± 10%
300 mg or more	± 7.5%

Disintegration test

Hard gelatin capsule	-	30 min
Soft gelatin capsule	-	60 min

Soft gelatin capsules

Method of manufacturing:-

(i) **Plate process:-** loss 15-20 percent content variation 20-40%

(ii) **Rotary process** ± 3%

(iii) **Reciprocating die process (Acogel)** accurately field powder dry solid into soft gelatin capsules

Capsule shell

Bloom and gel strength :- measure of cohesive strength of capsule shell

◆ Bloom strength is increased by ↑ molecular weight of gelatin , ↑ physical stability and ↑ Cost

range 150 to 250 gram

Viscosity:- Measure of molecular chain length determined by $6\frac{2}{3}$ % concentration of gelatin in water at 60 degree Celsius generally 25-45 Mili poise mostly 38 ± 2 mili poise

◆ Iron not more than 15 PPM

◆ Water gelatin ratio 1 : 1

Glycerine Gelatin ratio

0.4	:	1	Hard
0.6	:	1	Medium
0.8	:	1	Soft

Additional components

- ◆ **Methyl paraben and propyl paraben** :-used as a preservative in 4:1 concentration
- ◆ **Titanium dioxide**:- Opacifier agent
- ◆ **Ethyl vanillin** :-Flavouring agent
- ◆ **Fumaric acid**:- Aid solubility

Capsule contains

- ◆ pH 2.5 to 7.5 pH
- ◆ Less than 2.5 cause hydrolysis and leakage in Shell
- ◆ pH more than 7.5 can tan gelatin and affect solubility of shell

Base adsorption

- ◆ Number of grams of liquid base required to produce a capsulable mixture when mixed with one gram of solid
- ◆ It is used to determine capsule size
- ◆ Lower base adsorption high density means small capsule
- ◆ Soya lecithin 2- 3% used as a wetting agent to determine of base adsorption of vegetable oils

Capsule manufacturing

- ◆ Gelatin is weighted on printomatic scale and chilled 7°C in Pony mixer
- ◆ Homogenisation of soft gelatin is done by(i) Homoloid Mill (ii)stone Mill (iii)Hopper mill
- ◆ Moisture content of capsule shell is determined by toluene distillation method

- ◆ Shell thickness is directly proportional to product cost
- ◆ Seal thickness $\frac{1}{2}$ to $\frac{2}{3}$ of ribbon thickness
- ◆ Capsules are dried on 22- 30% relative humidity at 21 to 24°C by infrared dryers

Colour sorter:- by pneumatic conveyer

- ◆ Capsule reject when colour is not uniform

Note-Opacifying agents:-Increase the covering power of the film coats. Ex. Titanium dioxide, carbonate and oxide of magnesium, calcium sulphate, aluminium hydroxide, silicates etc