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CAPSULES





Intro

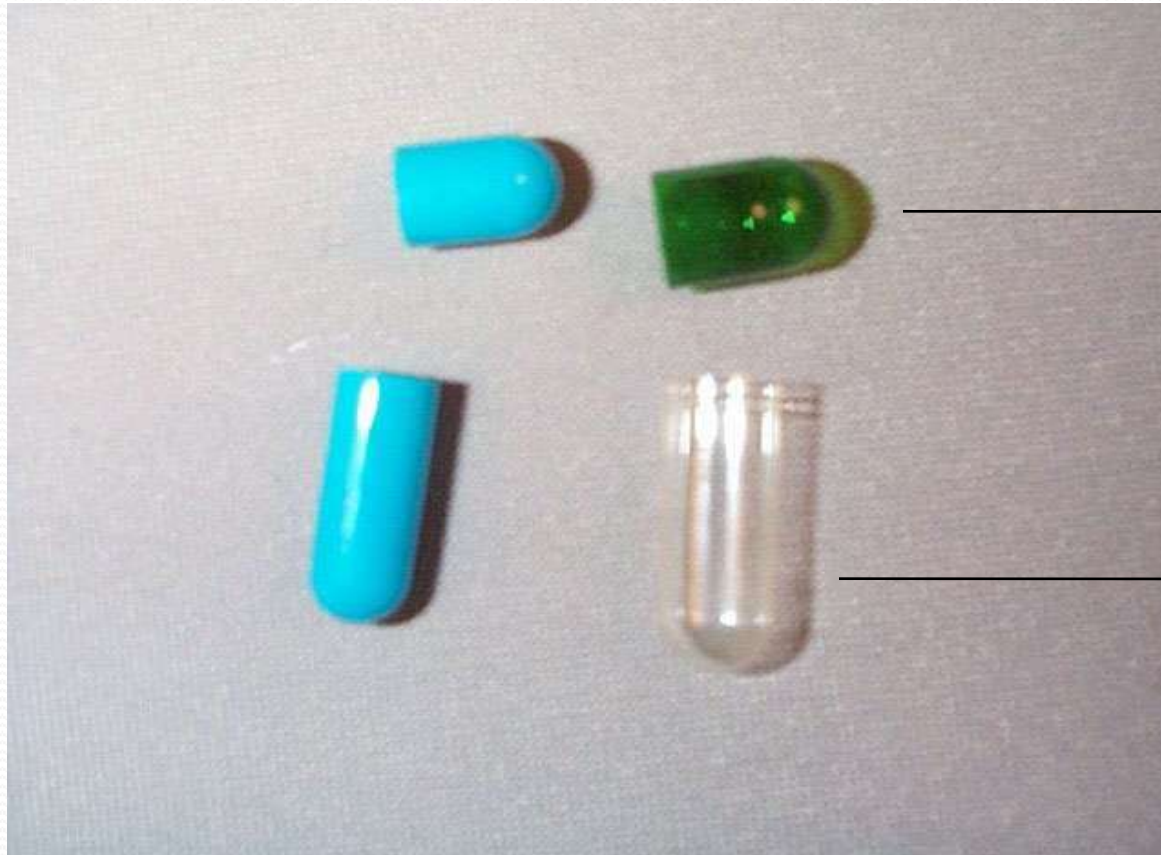


Hard gelatin capsule is also referred as “dry filled capsule” (D.F.C.) as their shell is hard and consist of two sections used for filling dry materials in body capsule.

Capsules are solid dosage form in which one or more medicaments are enclosed in a water-soluble, biodegradable shell made up of gelatin



PARTS OF CAPSULE



CAP

BODY

. Advantages of capsules for oral administration

1. Easy to swallow due to their smooth and slippery nature
2. Easy to handle and carry.
3. Can mask the unpleasant taste, colour and odour of drug using tasteless shell.
4. Better bioavailability than tablets and faster onset of action than tablets.
5. The shells are physiologically inert and easily and quickly digested in the gastrointestinal tract.
6. The shells can be opacified (with titanium dioxide) or coloured, to give protection from light

Hard Gelatin Capsules

- contain 12 - 16 % moisture
- typically filled with dry solids
 - powders
 - granules
 - pellets
 - tablets
- also contain
 - colorant
 - preservatives



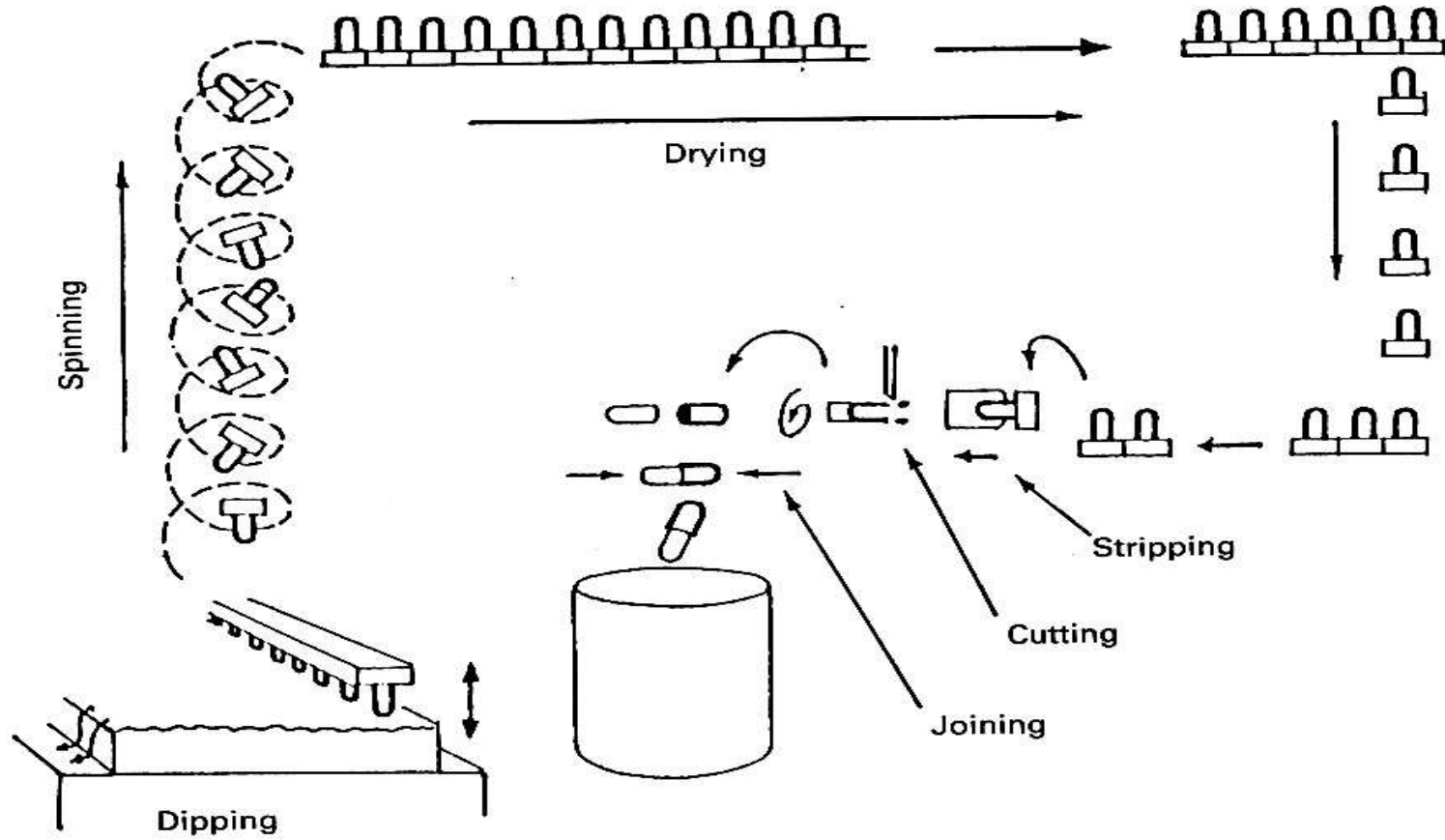
SIZE	VOLUME (cm ³)
000	1.37
00	0.95
0	0.68
1	0.50
2	0.37
3	0.30
4	0.21
5	0.13

MANUFACTURE OF EMPTY GELATIN CAPSULES

Steps involved in making empty gelatin capsules...

- Dipping
- Spinning
- Drying
- Stripping
- Trimming and Joining
- Polishing

Manufacture



Dipping :

Pairs of the stainless steel pins are dipped into the dipping solution to simultaneously form the caps and bodies.

The dipping solution is maintained at a temperature of about 50⁰C in a heated, jacketed dipping pan.

Spinning :

The pins are rotated to distribute the gelatin over the pins uniformly and to avoid the formation of a bead at the capsule ends.

Drying :

The gelatin is dried by a blast of cool air to form a hard shells.

The pins are moved through a series of air drying kilns to remove water

Stripping :

A series of bronze jaws strip the cap and body portions of the capsules from the pins.

Trimming and joining

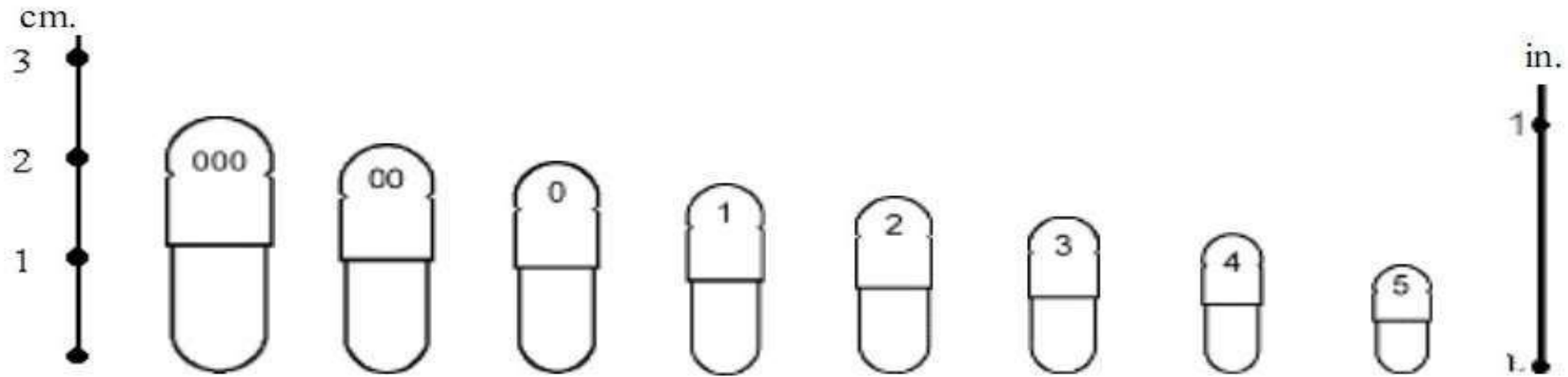
The stripped cap and body portions are trimmed to the required length by stationary knives.

After trimming to the right length, the cap and body portion are joined and ejected from the machine.

SIZE OF CAPSULES

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

SHADES OF CAPSULE



- *The largest size of the capsule is No:000.
- *The smallest size is No:5.
- *The standard shape of capsules is traditional, symmetrical bullet shape.

Filling hard gelatin capsules

- Consist of a couple of plates are capable of producing about 200 to 2000 capsules/hr.
- Hand-operated capsule filling machines or Feton capsule filling machine
- Filling hard capsule shells



FILLING OF HARD GELATIN CAPSULES

Various Filling Machine Available...

- Eli-lily and Co
 - Farmatic
 - Hofliger and Karg
 - Zanasi
 - Parke-Davis.
-
- These machine differ in there design and output

- A hand operated gelatin capsule filling machine consists of the following parts :-
- 1. A bed with 200-300 holes.
- 2. A capsule loading tray
- 3. A powder filling tray
- 4. A pin plate having 200 or 300 pins corresponding to the number of holes in the bed and cap holding tray.
- 5. A lever handle
- 6. A Cam handle
- 7. A plate fitted with rubber top.



Filling hard capsule shell

- Rectification
- Separating the caps from empty capsules
- Filling the bodies
- Scraping the excess powder
- Replacing the caps
- Sealing the capsules
- Cleaning the outside of the filled capsules
- 160,000 capsules per 8hour shift 6

Rectification

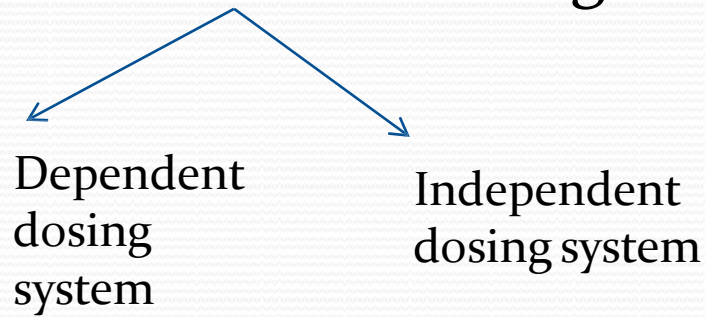
- The empty capsules are oriented so that all point the same direction i.e. body end downwards
- In general, capsules pass one at a time through a channel just wide enough to provide grip at cap end
- The capsules will always be aligned body end downwards, regardless of which end entered the channel first with the help of specially designated blades

Separation of caps from body

- The rectified capsules are delivered body end first into the upper portion of split bushings or split filling rings
- A vacuum applied from below pulls the body down into the lower portion of the split bushing
- The diameter of the bush is too large to allow them to follow body
- The split bushings are separated to expose the bodies for filling 8

Filling of powder formulations

- Bench -Scale Filling
- Industrial -scale Filling



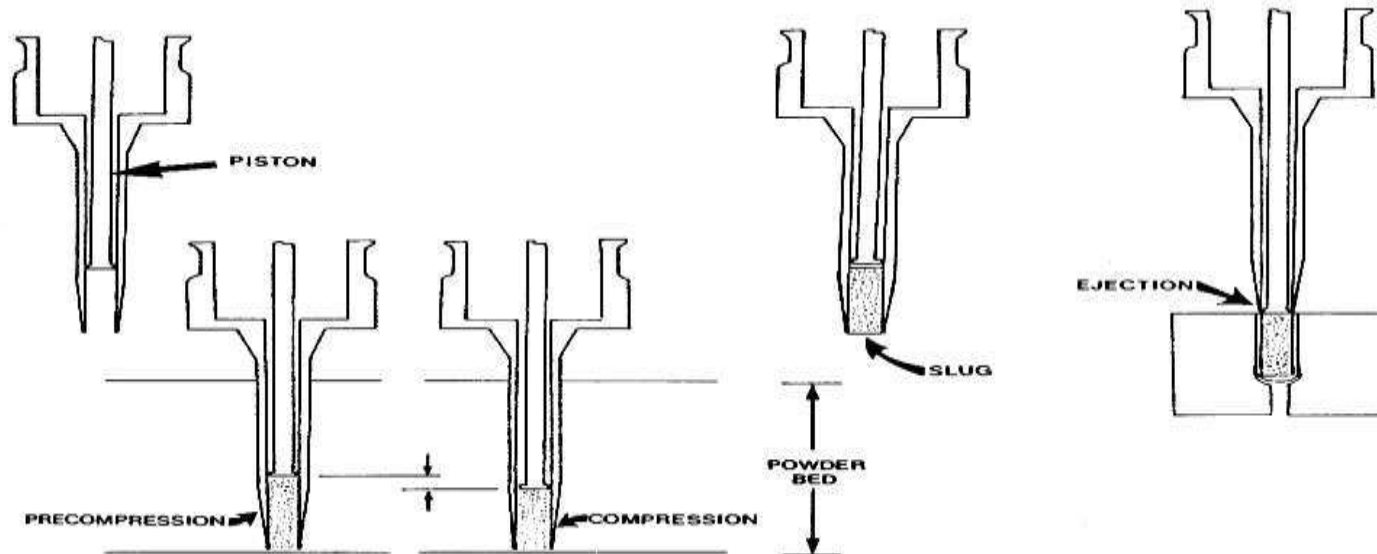
3 basic methods for powder filling

- auger or screw (dependent dosing system)
- Capsule body directly measure the powder

- Dosator (independent dosing system)
- Tamping finger and dosing disc (independent dosing system)
- Powder is measured in a special measuring device

Capsule Filling

- auger
 - semi-automatic operation
 - filling based on volume
 - need good powder flow properties
- dosator
 - fill based on weight
 - continuous operation



Capsule Filling

- dosing disc
 - filled based on weight
 - continuous operation

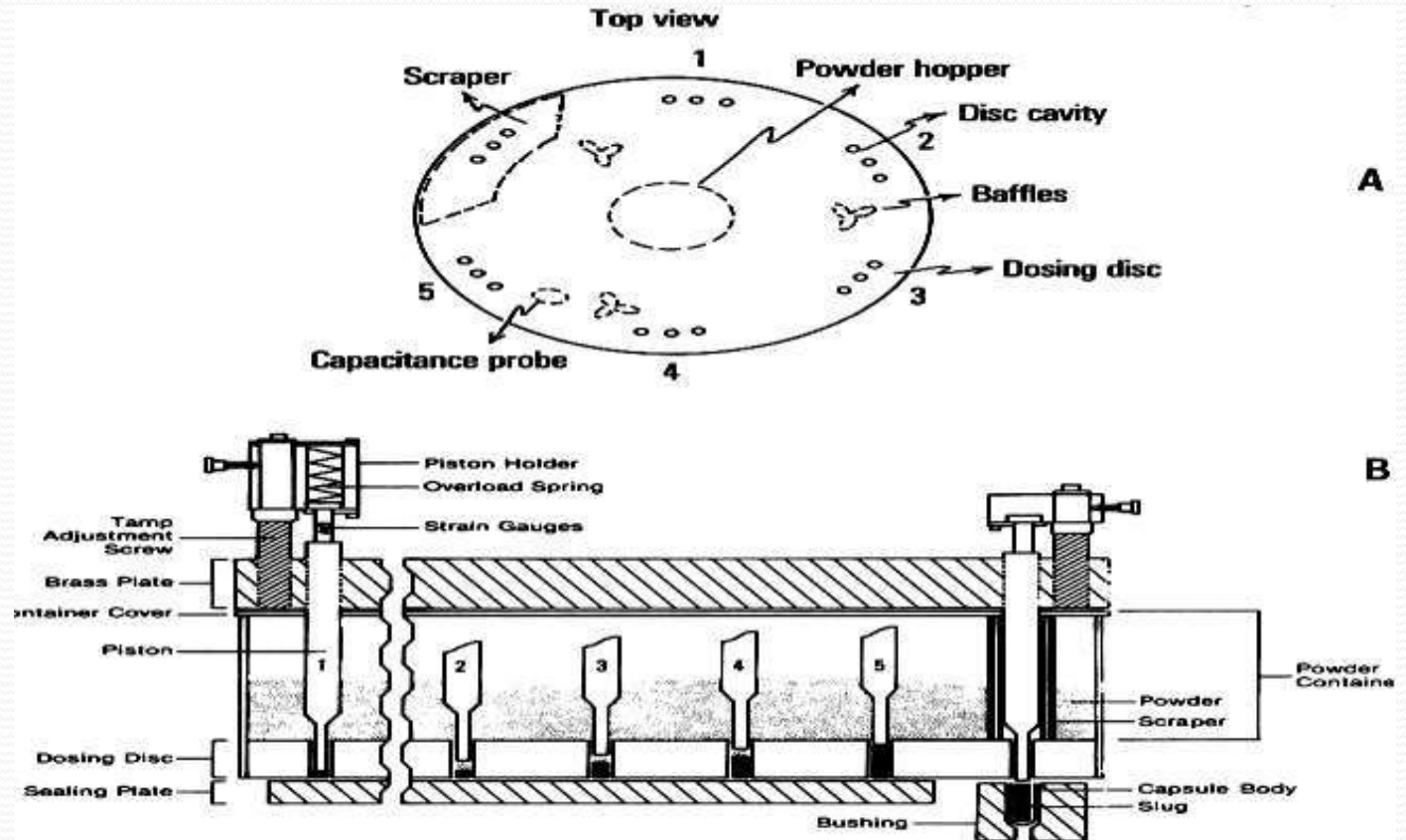


Fig. 10 Illustration of the dosing-disk-filling principle: (A) view looking down on the dosing disk; (B) side view (projected) showing progressive plug formation. Note the placement of strain gauges on the piston to measure tamping and plug ejection forces (see text). (From Ref. 37.)

Separation of caps from body

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Filling

Auger fill principle: Because the auger mounted in the hopper rotates at a constant rate, the rate of delivery of the powder to the capsules tend to be constant –

Flat blade auger

– Screw auger

E.g. Capsugel type 8 filling machine

Semiautomatic capsule machine

- (a) Sandwich of cap and body rings positioned under rectifier to receive empty capsules.
- Vacuum is pulled from beneath the rings to separate caps from bodies.
- (b) Body ring is positioned under foot of powder hopper for filling.
- (c) After filling the bodies, the cap and body rings are rejoined and positioned in front of pins. These pins push the bodies to engage the caps.
- (d) The plate is swung aside and the pins are used to eject the closed capsules

Filling • Vibratory fill principle

- In the powder, a perforated resin plate is positioned and connected to a vibrator
- The powder blend tends to be fluidized by the vibration of plate and assists the powder to flow into the bodies through the holes in resin plate 11



**ZANASI AUTOMATIC
CAPSULE FILLING MACHINE**



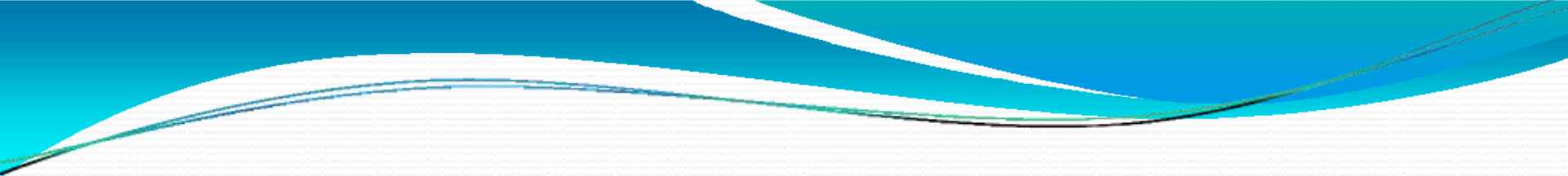
**HOFLIGER KARG AUTOMATIC
CAPSULE FILLING MACHINE**

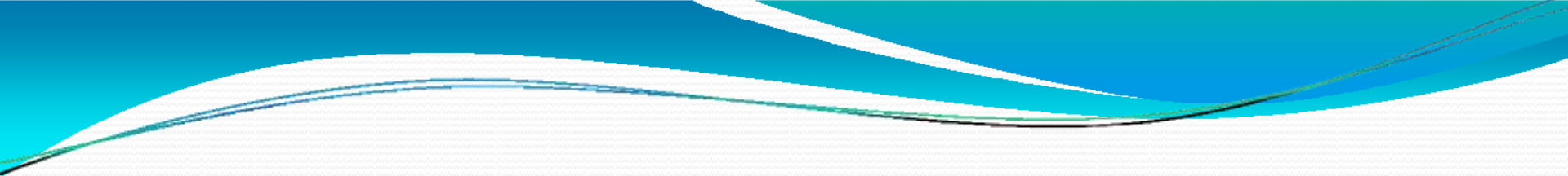
Filling • Piston tamp principle: •

- In this pistons or tamping pins lightly compress the individual doses of the powders into plugs(also called as slugs) and eject the plugs into empty capsule bodies
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- DOSATOR PRINCIPLE
- DOSING DISC PRINCIPLE 13

filling

- **Piston tamper principle**
- **DOSING DISC PRINCIPLE** a solid brass 'stop' plate is sliding down the dosing disc to close off the hole. Five sets of pistons compress the powder into cavities to form plugs

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- DOSATOR PRINCIPLE: it consists of cylindrical dosing tube fitted with movable piston.
 - The position of the piston is preset to a particular height to define a volume.
 - Powder enters the open end of dosator and is slightly compressed against the piston into a plug. ♣

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- HOFLIGER KARG AUTOMATIC
 - ZANASI AUTOMATIC CAPSULE FILLING MACHINE
CAPSULE FILLING MACHINE

Filling of hard gelatin capsules

- Equipment used
- Hofliger karg automatic
- formation of compacts in a die plate using tam ping pins to form acompact.
- ZANASI or martelli encapsulator
- Form slug in a dosator which is hollow tubewith plunger toeject capsuleplug

. FILLING OF HARD GELATIN CAPSULES

- Various Filling Machine Available
- • Eli-lily and Co
- • Farmatic
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- • Parke-Davis.
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Cleaning and polishing capsules

- Small amount of powder may adhere to the outside of capsules after filling.
- 1) Salt Polishing-cloth Dusting.
- 3) Brushing
- 4) Pan Polishing- Acela-cota pan is used to dust and polish.

Capsule polishing and capsule inspection machine



Storage, packaging, and stability

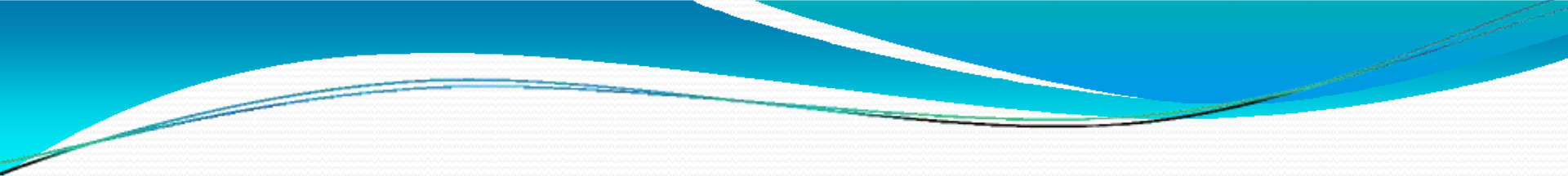
- Finished capsules normally contain an EMC of 13-16%.
- < 12% MC, the capsule shells become brittle
- >18% make them too soft
- To maintain a relative humidity of 40-60% when handling and storing capsules.
- QUALI-V, developed by Shionogi Qualicaps, is the first HPMC capsule developed for eventual use in pharmaceutical products

EVALUATION OF CAPSULES:

- Disintegration test
- Dissolution test
- Content uniformity
- Weight variation

Evaluation test

- Disintegration test for capsules Method :-
 1. The capsules are placed in the basket-rack assembly, which is repeatedly immersed 30 times per minute into a thermostatically controlled fluid at 37°C and observed over the time described in the individual monograph

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- Dissolution test for capsules
 - The apparatus, dissolution media and test is the same as that for uncoated and plain coated tablets

- Weight variation

- $W_{\text{capsule}} - W_{\text{emptied shell}} = W_{\text{content}}$

- 10 capsules labeled amount or average amount, $\pm 10\%$

- Content uniformity

- The amount of active ingredient should be within the range of 85% to 115% of the label amount for 9 of 10 capsules, with no unit outside the range of 70% to 125% of label amount.

Inspecting

- visual or electronic inspection → uniform in appearance
- Counting
- Counting tray
- Counting or filling machine
- Packaging
- Unit dose and strippackaging
- (sanitary, identifiable, safe)
- storing
- In a tightly closed container in a cool dry place

Recent Filling Equipments

- Roto-fill: - 2 lakh capsules/day
- Acco-fill: - 75,000 capsules/hr
- Roto-weigh
- Roto-sort: - 1,50,000 capsules/hr