



CAPSULE DOSAGE FORM : PREPARATION & EVALUATION (LAB.)

ASST.LEC. Fatimah Hasan

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INTRODUCTION

Capsule: is a solid dosage form consisting from gelatin shell filled with a blend of active ingredient and excipients which may be powder, semisolid or liquid That do not dissolve the gelatin shell.

(HGC)

- Which consist of body and cap that filled with powder

(SGC)

- Which consist of one piece that is filled with liquid.

INTRODUCTION :

Capsule shell

1. Gelatin .
2. Plasticizer PEG, glycerol and Sorbitol that presents in higher conc. in SGC than HGC.
3. Preservative Only in SGC to prevent contamination.
4. Colorant like soluble dyes or insoluble pigment.
5. Opaquing agent .

GELATIN :

- obtained from the skin, white connective tissue, and bones of animals.
- stable in air when dry but is subject to microbial decomposition when it becomes moist. Normally, **hard gelatin capsules contain 13% to 16% of moisture.**
- Readily soluble in biological fluids and body tissues.
- Good film forming that **undergo reversible** phase change from solid to gel in few temperature degree change.
- Because moisture may be absorbed by gelatin capsules and may affect hygroscopic agents within, many capsules are packaged along **with a small packet of a desiccant material (dried silica gel, clay, and activated charcoal) to protect against the absorption of atmospheric moisture.**

GELATIN :

- **below 10%** the capsule will be **brittle and shrink** to a point that it will not fit in the filling equipment.
- **above 15%** the capsule will be **so soft** and will cause size problems with the loss of mechanical strength.

ADVANTAGES OF CAPSULES OVER TABLET:

1. Mask bitter taste. more easily
2. swallowed since they are smooth and slippery.
3. Used for photosensitive drugs.
4. More economic due to no compression required and less excipients used.
5. No disintegrating agents added.

DISADVANTAGES OF CAPSULES:

1. Not used for highly soluble drugs such as KBr and NH_4Cl since the sudden release of such drugs in the stomach will cause high irritation.
2. Not used for **efflorescent and deliquescent** materials, since the **efflorescent** materials cause the capsule to soften, while **deliquescent** drugs may dry the capsule shell to excessive brittleness , which can be reduced by using small amount of inert oil in powder mixture.

(HGC) : EXCIPIENTS

Excipients	Example	Function
Diluent or Filler	Lactose, Microcrystalline cellulose, Starch	Provide bulk to powder lend to produce the proper capsule fill volume often provide cohesion to the powders
Disintegrants	Pregelatinized starch, Croscarmellose, Sodium starch glycolate.	Assist the breakup and distribution of the capsule's contents in the stomach.
Lubricant or Glidant	Fumed silicon dioxide, Magnesium stearate, Calcium stearate, Stearic acid, or Talc (about 0.25% to 1%)	Enhances flow properties
Wetting agent	Sodium lauryl sulphate	Improve dissolution

(HGC): CAP. SIZE

Capsule Size	Range of Powder Capacity
No. 5	60 – 130 mg
No. 4	95 – 260 mg
No. 3	130 – 390 mg
No. 2	195 – 520 mg
No. 1	225 – 650 mg
No. 0	325 – 910 mg
No. 00	390 – 1300 mg
No. 000	650 – 2000 mg

EXAMPLE : DETERMINE CAP. SIZE REQUIRED

RX: Ephedrine Hcl 1 gr

ft. cap

mitt. 1x cap

sig. One cap p.r.n

sol:

Calculate for 10 cap (9+1=10)

Note: 1grain=0.065 g

CONT.

Ephedrine Hcl 1 gr *10 cap=10gr (total wt. for 10 cap)

$$0.065\text{g} * 10 \text{ cap.} = 0.65\text{g} = (650\text{mg})$$

The size required for cap is (00) contain (650mg) from the table.

$$\text{Total wt. of powder} = 0.65\text{g} * 10 \text{ cap.} = 6.5\text{g}$$

Note : if we have more than one API in the Q. the total wt. of powder / n cap = wt. of each cap.

$$\text{The wt. for lactose added} = 6.5 - 0.65 = 5.85\text{g.}$$

HOME WORK :

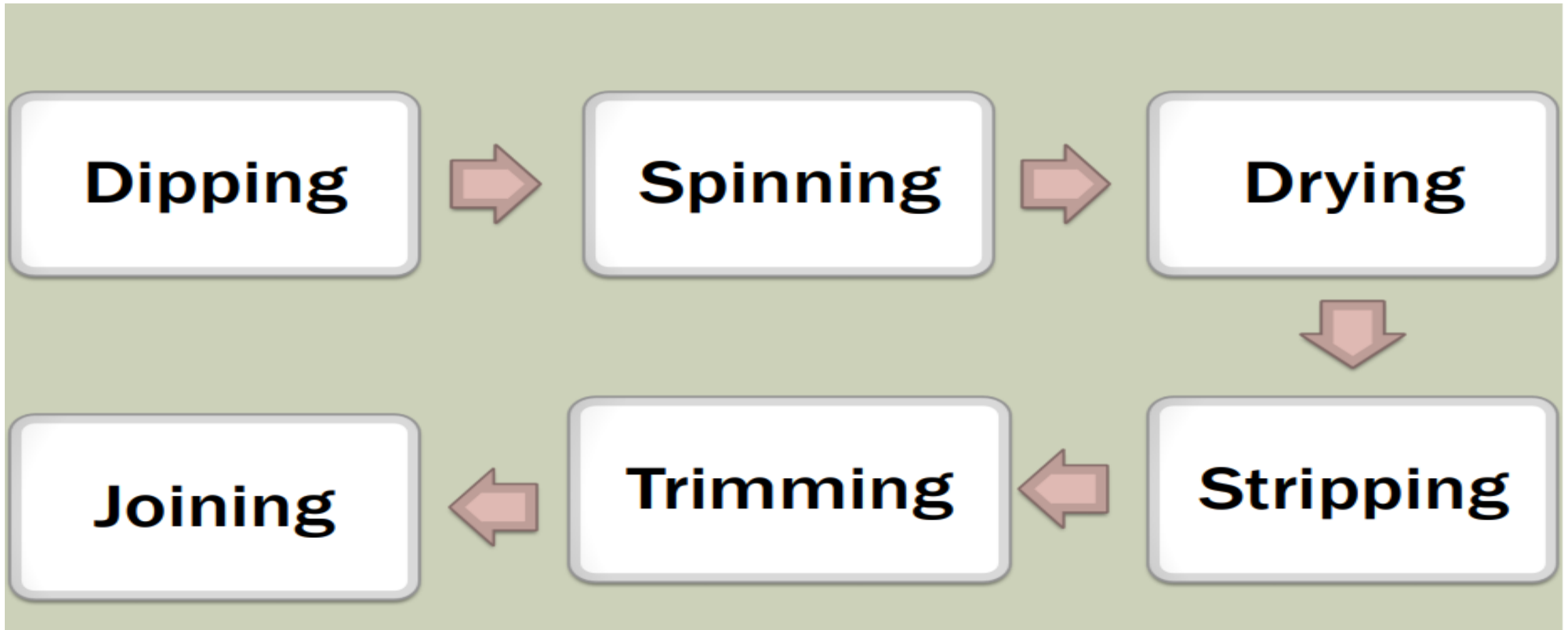
Bismuth carbonate gr x

Kaolin gr v

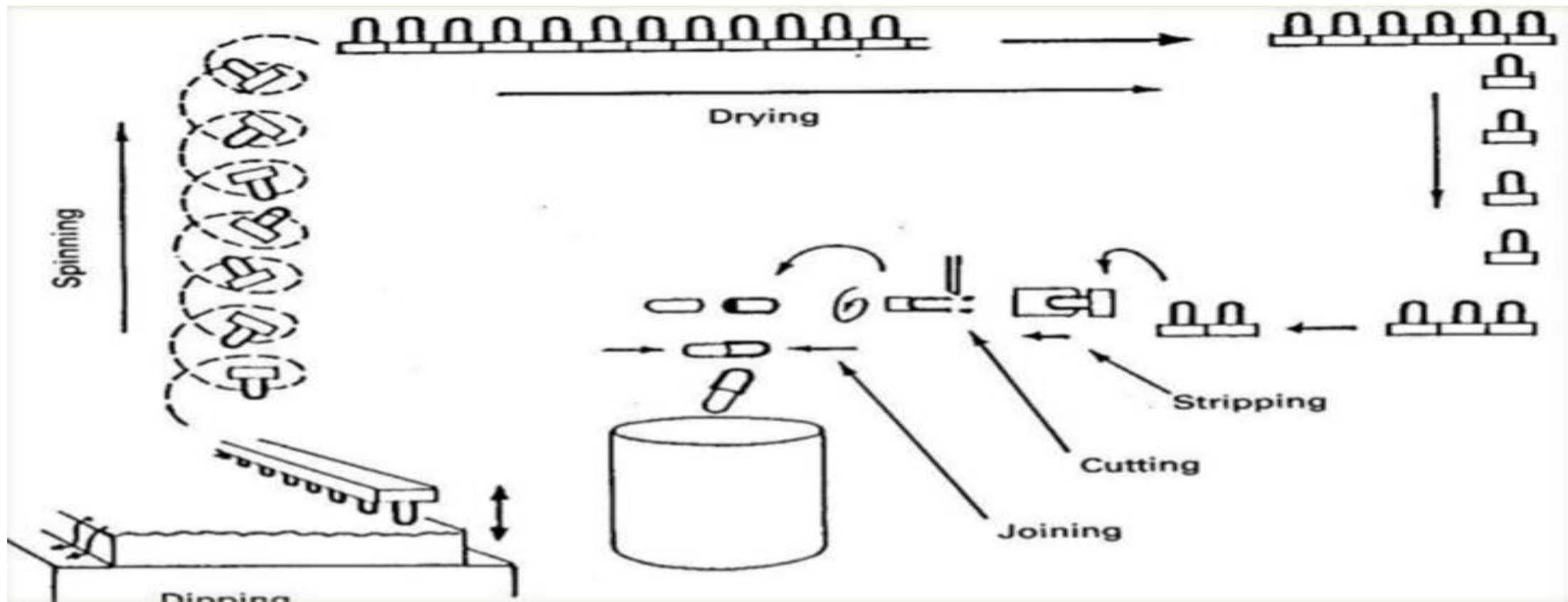
Mitt. V cap.

Sig. One cap. t.i.d.

PRODUCTION OF (HGC) SHELL:



CONT.



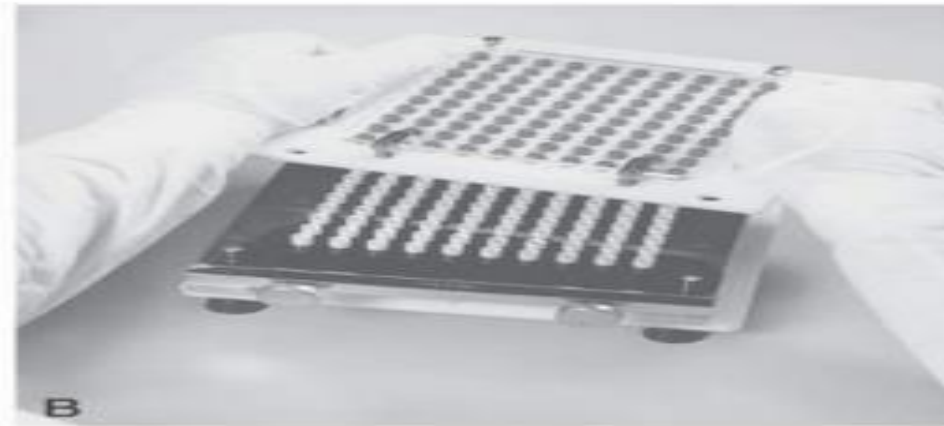
FILLING:

1- Electrical machine which is automatic.

2- Manual filling machine which is used for small scale the produce 20-36 capsules.

3- Hand filling by the dipping technique.

THE FETON CAPSULE FILLING MACHINE :



(SGC)

- a. made of gelatin to which **glycerin or sorbitol** has been added.
- b. contain **more** moisture than hard capsules, may have a preservative, such as methyl paraben and/or propyl paraben, to retard microbial growth.
- c. more elegant and easily swallowed by patient than HGCs.
- d. **preparation** : Soft gelatin capsules may be prepared by the **plate process**, using a set of molds to form the capsules, or by the more efficient and **productive rotary die processes** by which they are produced, filled, and sealed in a continuous operation.

EVALUATION OF CAPSULES:

1. Content uniformity test:

It's done by taking 10 capsules and assay each individually by specified procedure, if 9 out of 10 within

the requirement of $\pm 15\%$ (85%-115%) limits and the tenth tablet is not outside $\pm 25\%$ (75%-125%) so the batch should be accepted. While if 2 capsules out of 10 fall outside the range $\pm 15\%$ so take 20 capsules and assay them individually and take the average of 30 capsules, so the requirements are met if 27 capsules in the $\pm 15\%$ range and only 3 capsules in the $\pm 25\%$ range.

CONT.

2. Disintegration test:

disintegration time is measured when the capsule shell rupture and all the contents pass through the mesh, in order the batch to be accepted the time must be less than 30 minutes.

Capsules	Disintegration Time (min)
Hard capsules	30
Soft capsules	30
Rectal capsules	30
Vaginal Capsules	30
Gastroresistance Capsules	60

FACTORS AFFECTING THE DISINTEGRATION TIME:

- 1- The type of the gelatin shell.
- 2- The humidity of the capsule shell.
- 3- Dissolution media.
- 4- The type of the powder used.
- 5- The type and the amount of the binder used.

3. LEAK TEST:

Procedure(PT-LT apparatus):

Samples are placed into the desiccator's housing and the lid is placed in position. The pump starts to produce a vacuum inside the desiccator and the sample is held for a pre-set time. After the test, the tested package should keep its shape indicating a good seal. It is also possible to use a colored dye solution (normally Methylene Blue). If there are any holes in the seal, the dye penetrates the contents of the packaging.

PT-LT APPARATUS:



A rectangular area with a soft, yellow watercolor-style background. The colors are warm and blended, with some darker yellow and orange tones towards the edges, creating a gentle gradient effect.

Thank You