

**INDUSTRIAL PHARMACY-I****UNIT III-CAPSULES****CLASS:21****TOPIC Importance of base adsorption and minim/gram factors, production****CAPSULE MANUFACTURING**

- Base adsorption is defined as the number of grams of liquid base required to produce a capsulated mixture (medicament) when mixed with 1 gram of solid (API).
- Base adsorption = Weight of base/Weight of solid
- Solids that are not sufficiently soluble in liquids are capsulated as suspensions. Such materials should be 80 mesh or finer in particle size.
- Base Adsorption •
- The base adsorption mixture is milled or homogenized, and deaerated (a desiccator under vacuum is suitable), and the specific gravity is taken.

Base Adsorption (Solid~API) (Liquid Base) Capsulated mixture = 1 gm =?

When the mixture tends to stop flowing, note down the weight of liquid base

Influenced by factors as –

- solid's particle size and shape,
- physical state (fibrous, amorphous, or crystalline),
- density,
- moisture content,
- and oleophilic or hydrophilic nature.
- In the determination of base adsorption solids must be completely wetted by the liquid base. For glycol and nonionic type bases, the addition of a wetting agent is required, but for vegetable oil bases, complete wetting of the solid(s) is not achieved without an additive. Soy lecithin, at a concentration of 2 to 3% by weight of the oil, serves excellently for this purpose. Base Adsorption

Solid + liquid base (ex. PEG400) = Capsulated mixture - it can be used to determine minimum capsule size but Suspending agent (Ex. Liquid wax) or Gelucire 44/14 (prevent crystallization) is added to make the mixture stable, uniform,

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bioavailability and lubricity.

- Mostly used suspending agent for oily bases is wax mixture, and in nonoily bases, the polyethylene glycols 4000 and 6000. Minim per gram factor

Minim per gram factor 1ml=16.23minim

B.PHARMACY 5<sup>TH</sup> SEMESTER (2025-2026)

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*Plate process:* It is the oldest process, contains sets of plates containing die packets.

*Rotary die process*

*Reciprocating die process*

*Accogel machine* is unique in that it is the only equipment that accurately fills **powdered dry solids** into softgelatin capsules.

## PROCESS

*Gelatin preparation department*

- (i) Weighing of gelatin Mixed in  
Weighing of other liquids chilled at 7°C Pony mixer
- (ii) The resultant fluffy mixture transferred to melting tanks and melted under vacuum at 93°C
- (iii) A sample of the resulting fluid mass is visually compared with a color standard, and additional colorants are added if required.
- (iv) The mass is then maintained at 57 to 60°C before and during capsulation process.

*Material preparation department*

- (i) *Blending* → milling or homogenization

*Equipments:* Homoloid mill

Stone mill

Hopper mill

Urschel comitrol

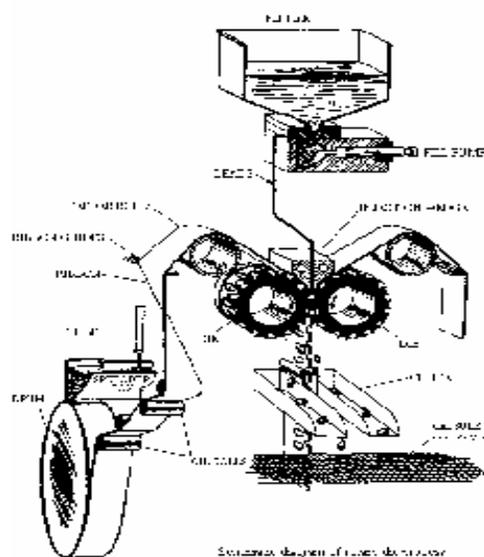
- (ii) *Deaeration* → all mixtures are subjected to deaeration by  
to achieve uniform capsule fill weight  
and it reduces oxidation of the product.

Most liquids and suspensions may be deaerated by means of equipment designed to expose thin layers of the material continuously to a vacuum (29.5 mm Hg).

- (iii) After deaeration the volatile ingredients are added and blended.

*Material filling by rotary die process*

- The gelatin mass is fed by gravity to a metering device (spreader box), which control the flow of the mass onto air cooled (13 to 140C) rotating drums. Gelatin ribbons of controlled thickness are formed. The wet film thickness may vary from 0.022 to 0.045 inch.
- The ribbons are fed through mineral oil lubricating bath, over guide rolls, and then down between the wedge and the die rolls.



- The materials to be encapsulated flows by gravity into a positive displacement pump. The pump accurately meters the material through the lead sand wedges and into the gelatin ribbons between the die rolls. The bottom of the wedge contains small orifices lined up with the die pockets of the die rolls.
- The capsule is about half sealed when the pressure of the pumped material forces the gelatin into the die pockets, where the capsules 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 to 40°C) of the ribbons by the wedge.
- Immediately after the manufacture, the capsules are automatically conveyed through a naphtha wash unit to remove the mineral lubricating oil.

The washed capsules may be automatically subjected to a preliminary infrared drying step which removes 60 to 70% of the water that is to be lost, or may be manually spread directly on trays. All the capsules are allowed to come to equilibrium with forced air conditions of 20 to 30 % relative humidity at 21 to 24°C.