TABLET COATING

Lec. 8

TABLET COATING PRINCIPLES

History: Tab. coating starts with Rhazes (coated food) in 800s then developed by Frenches (sugar coat) in 1800s and finally Abbott marketed (film coat) in 1953.

- **Objectives for tablet coating based as following:**
  1. Mask the taste, odor or color of the drug
  2. Provide physical and chemical protection for the drug
  3. Control release of drug from tab.
  4. Protect drug from gastric environment of the stomach with an acid resistant enteric coating.
  5. Incorporate another drug or formula in the coating to avoid chemical incompatibilities or provide sequential drug release.
  6. Improve pharmaceutical elegance by using special colors and contrasting painting.

PRIMARY COMPONENTS IN TAB. COATING

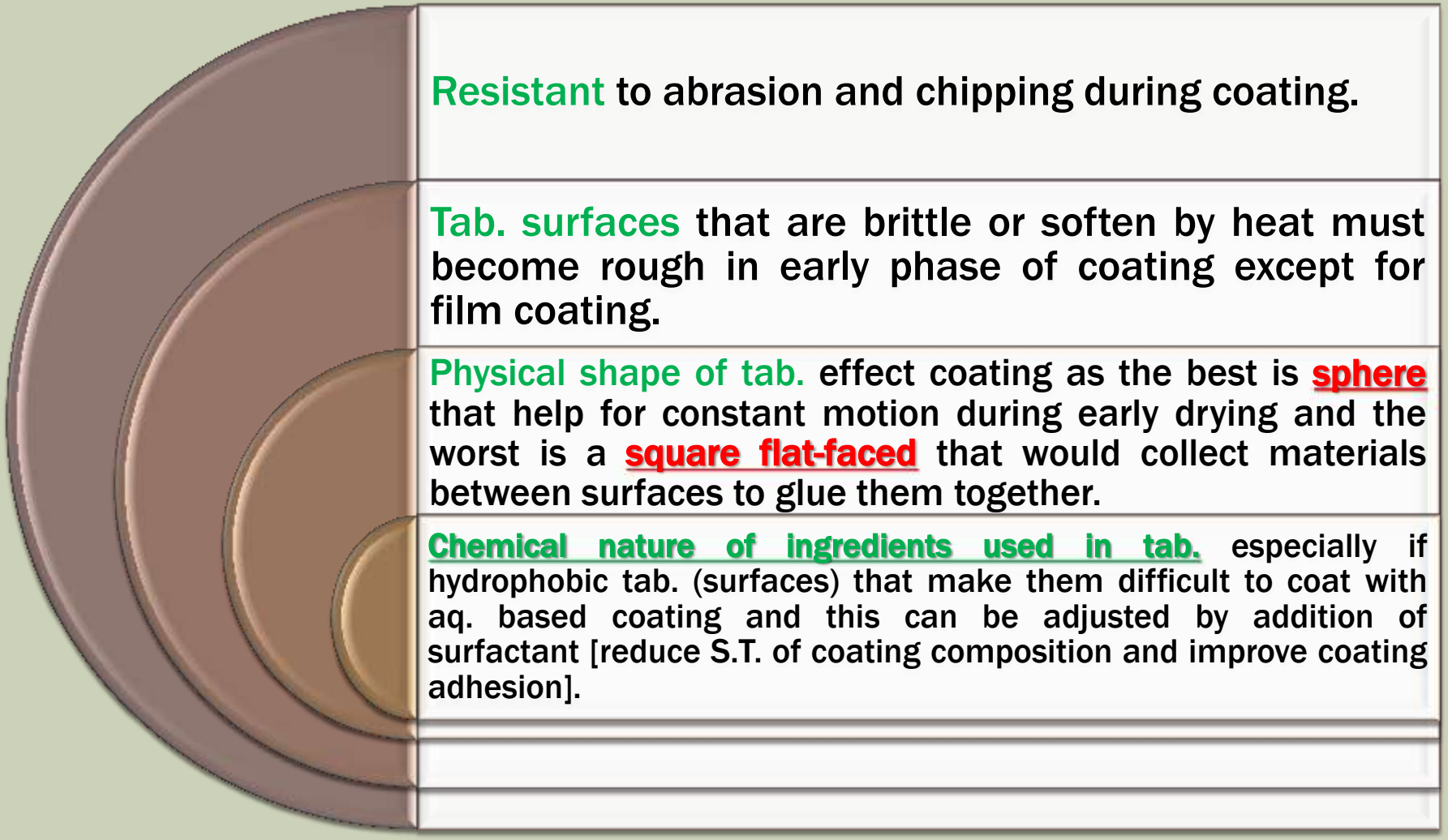
1. Tab. properties

2. Coating process

- Coating equipment
- parameters of coating process
- Facility and ancillary equipment
- Automation in coating processes

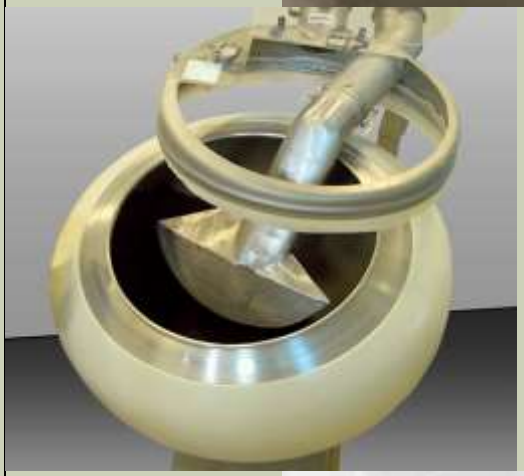
3. Coating compositions (Tab. Coating Processes)

1. TAB. PROPERTIES



2. COATING PROCESS

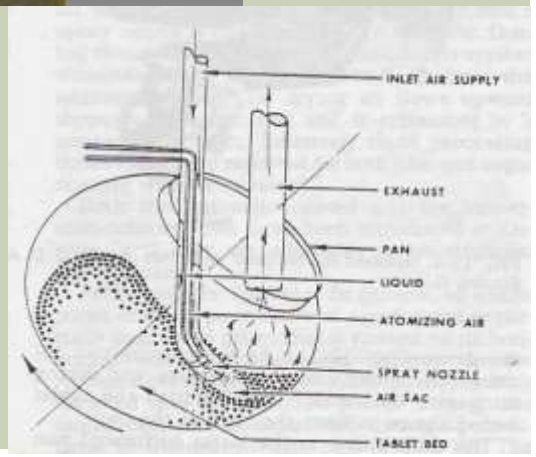
1. **Equipment** (several types including):
   a) Conventional or Standard coating pan
   b) Perforated coating pan
   c) Fluidized bed (air suspension)



a) Conventional coating pan (Pellegrini pan, immersion sword and immersion-tube syst.)

Circular metal pan mounted on a stand and supplied by with heated air through the front of pan; thus the coating solution applied to the tablet by ladling or spraying.

The spraying is the best as it reduces drying time in sugar coating and continuous application of solution in film coating.



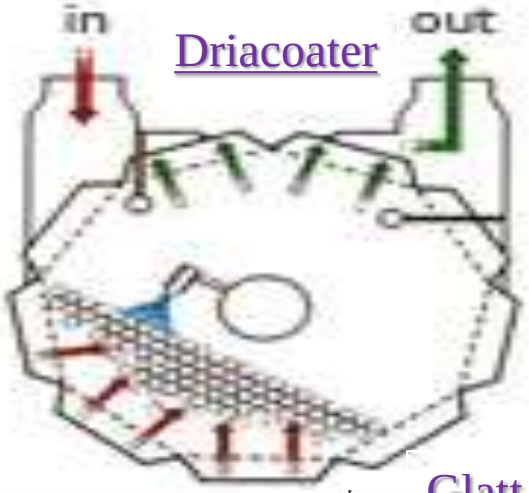
b) Perforated pan system (Accela-Cota, Hi-Coater sys., Driacoater and Glatt coater)

Drying air directed into the drum by passing through tab. bed and exhaust through perforation in the drum, while coating solution is applied to the surface of rotating bed of tab. through spray nozzles inside drum.

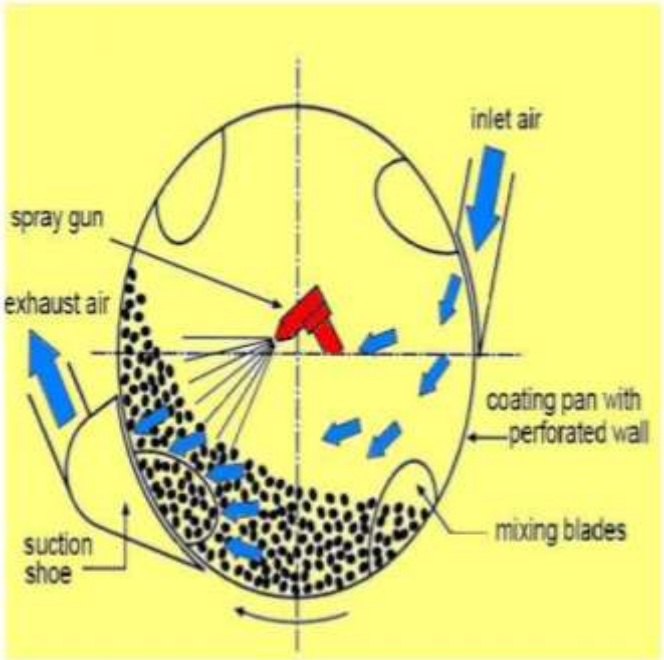
Uses: high coating capacity and drying system

Type of coats: sugar and film coat

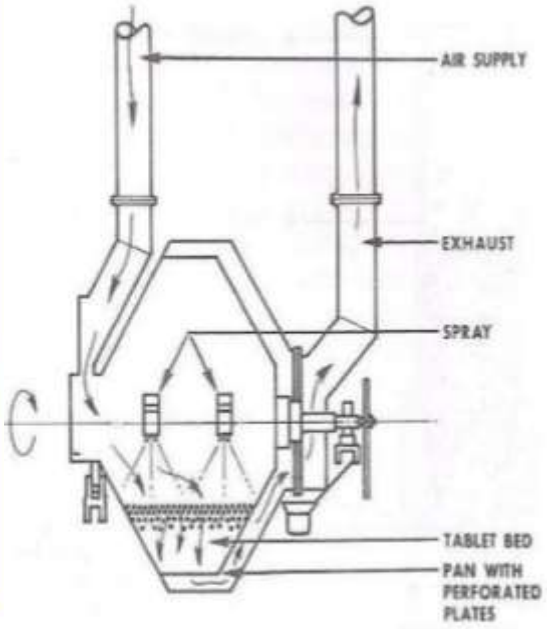
Driacoater



ACCELA-COTA



HI-COATER SYSTEM

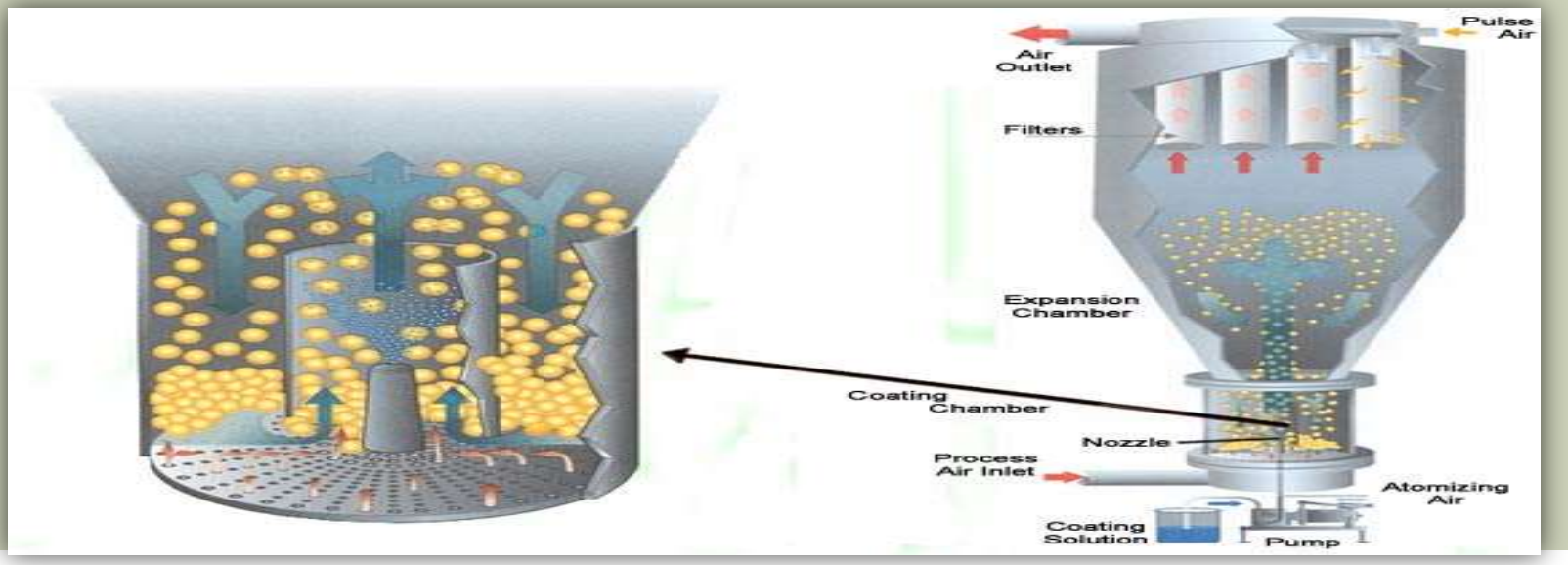


Glatt coater

c) Fluidized Bed (Air Suspension)

Uses: highly efficient drying in addition to coating

Disadvantages: Tab. core that are friable and prone to chipping and edge abrasion are difficult to coat even under optimum conditions of fluidized bed system due to rough tab.-tab. impact and tab. chamber impact.



2. Parameters

i. Air capacity: represent quantity of water or solvent moved during coating process which depend on quantity of air flow, temp. of air and the quantity of water that the inlet air contain.

ii. Coating composition: the coating contains the ingredients that applied to tab. surface and the solvents which act as carrier for ingredients.

iii. Tablet surface area: total S.A./ wt. decrease significantly from smaller to larger tablets.

iv. Equipment efficiency: 60% sugar coating is acceptable while film coating is not.

3. Facility and Ancillary equipment

Facility required for any coating operation is determined by GMP like (adequate space, safety, treatment of exhaust)

4. Automation

Achieved through a series of sensors and regulating devices for temp, airflow, spray rate and pan speed, a feed back control of the process is maintained.

3. TABLET COATING PROCESSES

The last critical step in tab. production representing successful application of coating solution to the tab.

Benefit: *(providing visual characteristic and the quality for the product).*

Choosing type of tab. coating process depend on:

1. **Type of coat applied (sugar or film)**
2. **Toughness of tab. core**
3. **Economic of the process**

Note: SUGAR COATING IS STILL WIDELY USED BECAUSE OF THE EXCELLENT TAB. APPEARANCE IT ACHIEVES.

SUGAR COATING

Using pan-ladling, spray coating and automation to yield elegant and highly glossed tab.

THE BASIC SUGAR COATING PROCESS INVOLVES THE FOLLOWING STEPS:

1. Water proofing and sealing
2. Sub-coating
3. Syruping (smoothing)
4. Finishing (coloring)
5. Polishing

Note: **sugar coating tend to be long (few hrs to few days) and vigorous, then the cores should be relatively resistant to breakage, chipping and abrasion.**

1. Water proofing and Seal coating

Prevent moisture penetration into tab. core and overwetting

Softening or disintegration and affecting physical and chemical stability in pan-ladling while in spray process does not occur due to adjustment of subcoating application.

Ex: **Shellac** (increasing dissolution and disintegration time due to polymerization) but in **zein** this will not occur.

2. Subcoating

To round edges and build up tablet size (increasing tab. wt. by 50-100%)

process: applying sticky binder solution followed by dusting of subcoating powders then drying until the edges covered and the desired thickness achieved.

3. Syruping and Finishing Coat (smoothing/coloring)

Cover and fill up imperfections on tab. surface caused by subcoating and impart desired color to the tab.

(1st syrup coat [grossing syrups- containing suspended powder] then subsequent syruping steps including dye and finally syruping or a finishing step –a few clear coats of syrup applied-)

Note: no color should be added until tab. Become smooth surface since premature color application to rough surface produce mottling in final coated tab.

4. Polishing

The desired luster is obtained by:

- Standard coating pan
- Canvas-lined polishing pan (by applying powdered carnauba or beeswax or warm solution of these waxes in naphtha or suitable volatile solvent).

FILM COATING

Methods of preparation:

1. Pan-pour methods:

Not favored method for film coating

Disadvantages:

1. Slow due to using of too viscous components to be sprayed.
2. Depend on skill and technique of operator to balance the steps.
3. Required additional drying to remove solvents.
4. Not suitable for aqueous based film coatings due to overwetting that causes many problems range from surface erosion to product instability.

2. Pan-spray methods

Improving efficiency of film coating by allowing for automated control of liquid application through nozzles.

Process variables:

i. Pan variables (pan design/baffling, speed and pan load)
ii. Process air (air quality, temp., air flow rate/vol./balance)
iii. Spray variables (spray rate, degree of atomization, spray pattern, nozzle-to-bed distance)

I. PAN VARIABLES

Affect uniform mixing to deposit same quantity of film on each tablet.

- Tablet coating adds only 2-5% in weight.

Ex: A- baffling: ensure adequate mixing if not then chipping and breakage occur.

B- pan speed: affects the velocity of tab. pass under spray.

1. **Low speed** ⟹ overwetting and sticking of tab. to each other or to pan.
2. **High speed** ⟹ not allow enough time for drying before reintroduced to spray then rough coating on tab.

❖**3-10 rpm for aqueous film** coating to allow for coat application and drying

❖**10-15 rpm** in large coating pan **for non-aqueous film** coating.

II. SPRAY VARIABLES

The spray variables that should be controlled are the followings:

1. Rate of liquid application
2. Spray pattern
3. Degree of atomization

All of three variables are independent.

The systems in spray coating and their effects on spray variables:

a) Airless, high pressure sys.: **affect 3 variables by fluid pressure and nozzle design.**

b) Air atomized, low pressure sys.:

   i. **Rate of liquid flow** affected by liquid pressure and liquid orifice size

   ii. **Spray pattern and degree of atomization** affected by atomizing air pressure, air volume and shape and design of air jet in relation to fluid stream.

1. Spray rate depends on:

a. Mixing and drying efficiency
b. Coating formula
c. Core characteristic

Notes:

1- band of spray should be spread evenly over the tablet mass.

2- In larger pans, more nozzles must be added to cover the tab. bed width.

2. Spray pattern

i. **Too wide:** results in application of coating to the pan surface rather than tab.

⇩

wasting products and lower coating efficiency

ii. **Too narrow:** results in localized overwetting and tab-to-tab. coating uniformity will be poor.

⇩

Tab. Should pass over spraying area several times for adequate coating

3. **Nozzle to bed distance** **having many benefits:**
   a. Affects spray width by moving nozzles closer or farther away from tab. bed
   b. Affects quantity of coating applied to individual tab. pass under spray.

4. **Atomization** **(process whereby liquid stream finely subdivided into droplets) can be controlled by:**
   i. **Adjustment fluid pressure in airless high pressure system.**
   ii. **Adjustment of air stream and air volume in low pressure system.**

Notes on Atomization:

1. **if atomization too fine** ⟹ droplets dry before reaching tab. bed (spray-drying)

   ⇩

   Roughness on tab. surface or excess dust in pan

2. **Insufficient atomization** ⟹ too large droplets reaching tab. surface ⇒ overwetting

   ⇩

   Sticking, picking or rough (orange-peel effect)

III. PROCESS AIR VARIABLES

Process air variables like (temp., volume, rate, quality and balance) should be controlled for OPTIMUM DRYING ENVIRONMENT FOR PARTICULAR COATING.

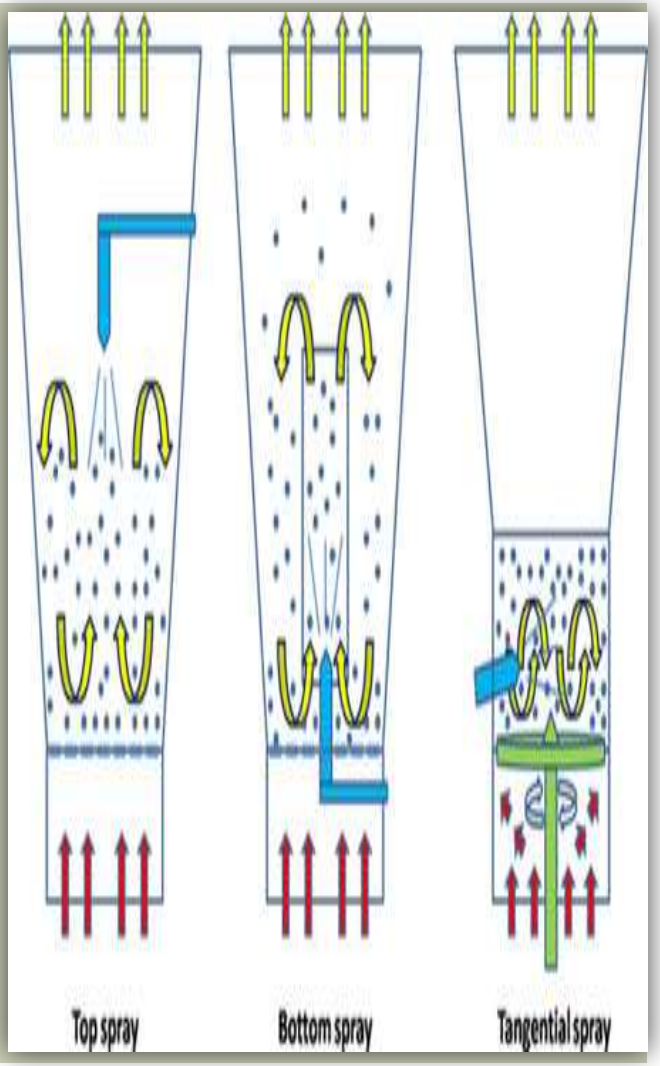
a. **Upper temp. limits** depends on sensitivity of film former and product core.
b. **Air volume and rate limits** depend on overall design of the air-handling system and coating equipment.
c. **Quality of supplied air** like having some degree of dehumidification since in moisture content of incoming air could alter coating and drying conditions
d. **The balance between supply and exhaust air-flow should be controlled** to maintain all dust and solvent contained within the coating system.

3. Fluidized Bed Process

THIS PROCESS USED FOR RAPID COATING OF TAB. AND IT DEPENDS ON:

a. **Coating solution formulations**
b. **Air used to move tab. in coating process**

a. **Fluidization (coating solution) affected by:**
   i. Chamber design and process air
   ii. Tab. size, shape, density and quantity of load
   iii. Increase in wt. or by change in frictional characteristics of tab. during coating and thus periodic control of rate and air volume for optimum fluidization.



b. Volume and rate of process air can be controlled by:

1. Variable speed blower
2. Using dampers to keep tab. mass in constant (fluid) motion inside the chamber.

Note: **if too high airflow** ⟹ tab attrition and breakage.

If too low airflow ⟹ mass does not move fast enough through the spray region and overwetting occur.

- **Monitoring inlet and exhaust air temp.** to controlling rate of application of coating solution

since

evaporation of solvent causes the exhaust air temp to be cooler than the inlet.


THANK YOU!