The logo of Galgotias University is a stylized 'G' composed of three curved, overlapping bands in shades of yellow, blue, and red, set against a light grey circular background.

MODULE 2:Tablets

Lecture 5

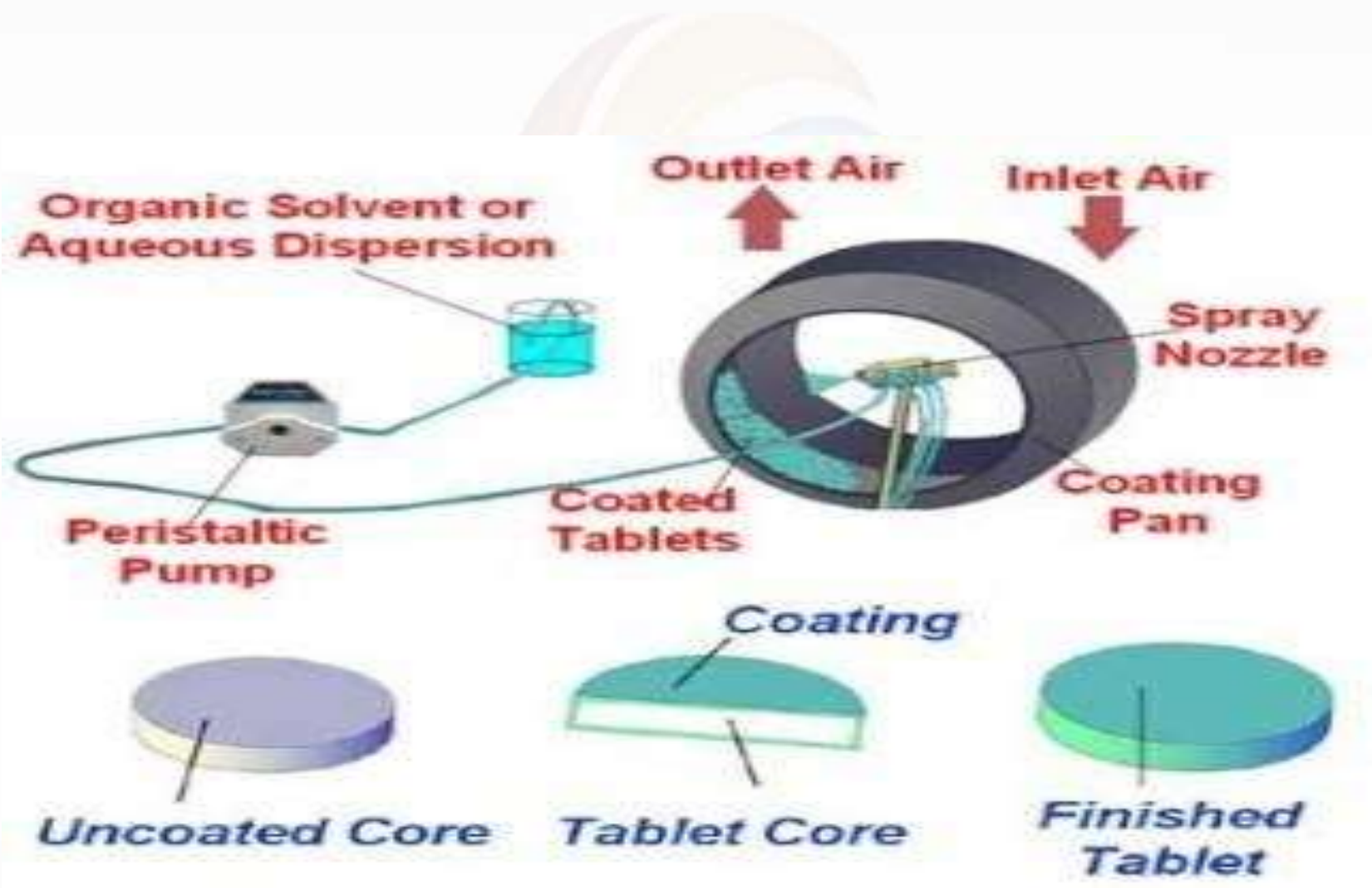
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DISCLAIMER

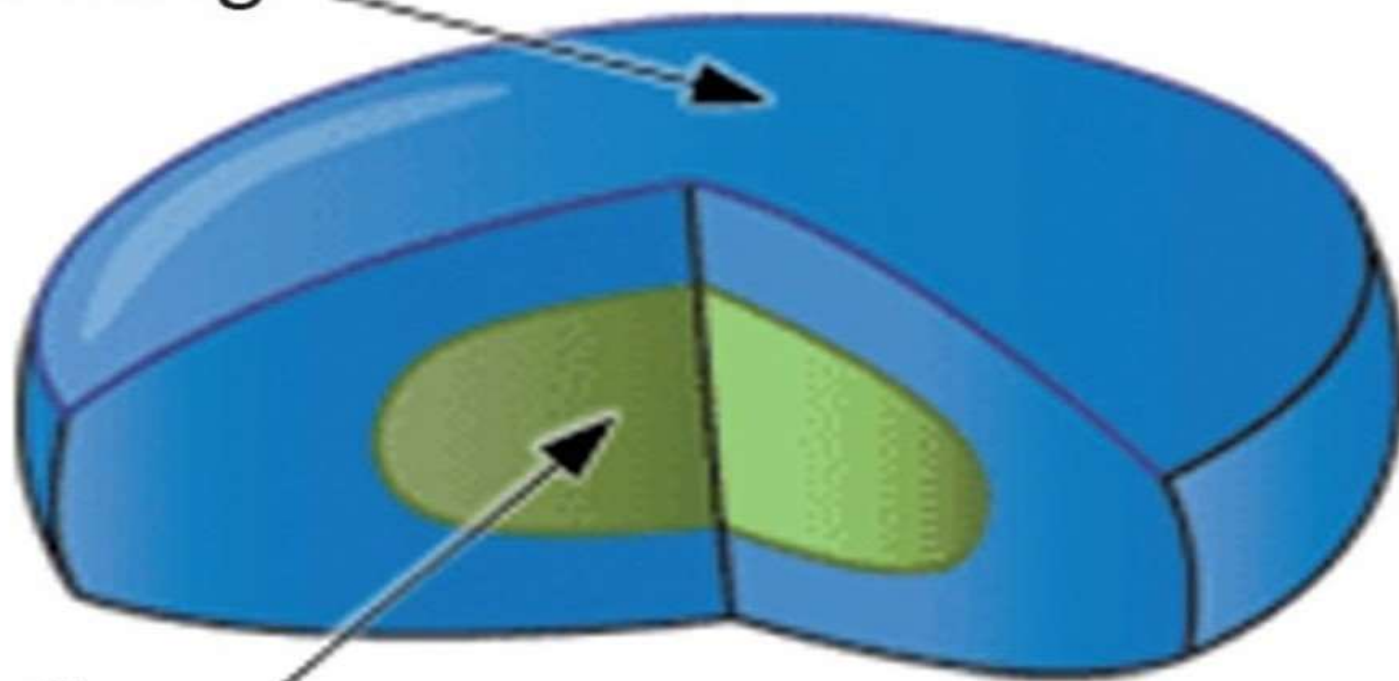
All the content material provided here is only for teaching purpose

The logo of Galgotias University is a stylized, circular emblem. It features a central white swirl that transitions into a blue swirl, which then transitions into a yellow swirl, and finally into a red swirl. The entire emblem is set against a light brown background.

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Coating



Core

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TABLET COATING

“Tablet coating is the application of coating material to the exterior of a tablet with the intention of conferring benefits and properties to a dosage form over the uncoated variety.”

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Advantages of Coating???

- Mask Bitter taste
- Mask unpleasant odour.
- Protecting the drug from surroundings.
- To increase the Stability.
- Handling & ease of ingesting by patients.
- Mechanical protection from breakage.
- Avoid Light incompatibility.
- Protection from Environmental Oxidation.
- In- elegant core.
- To modifying the drug release profile.
- For Product identity.

Coating for Processing

- ⊕ Increase packaging speed
- ⊕ Reduces damage during the packaging process
- ⊕ Printing efficiency and clarity
- ⊕ Product identification
- ⊕ Reduced changeover and clean down time
- ⊕ Reduces operator exposure to active substances

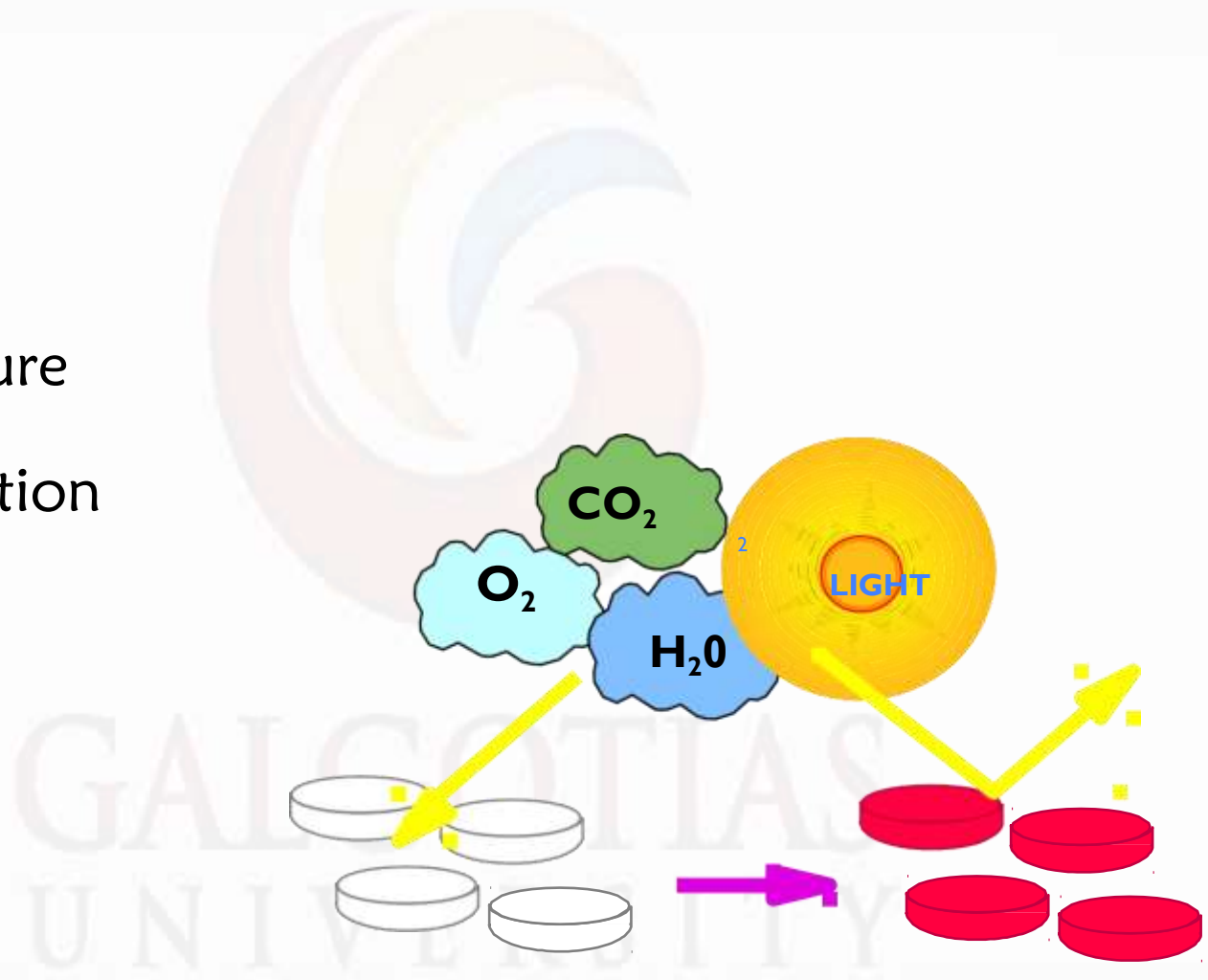
Coating for Marketing

- ⊕ Allows product to stand out from the competition
- ⊕ Colour and tablet shape for branding and trademark



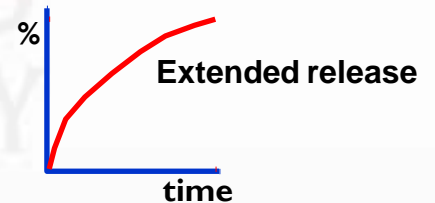
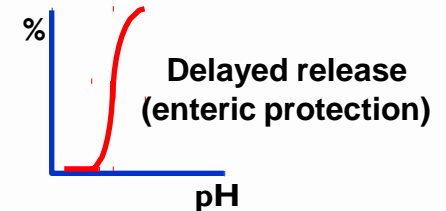
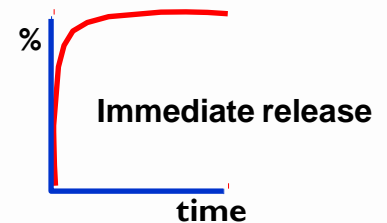
Coating for Product Stability

- ⊕ Light
- ⊕ Moisture
- ⊕ Oxidation



Coating for Release

- ⊕ No functional coat.
- ⊕ Provide release of drug at various GI sites depending on pH.
- ⊕ Change rate of release of active e.g. control rate of active release over 24 hours.



Coating for Consumers

⊕ Patient compliance is affected by a product's :

- Ease of Use
- Identity
- Efficacy
- Taste
- Odour

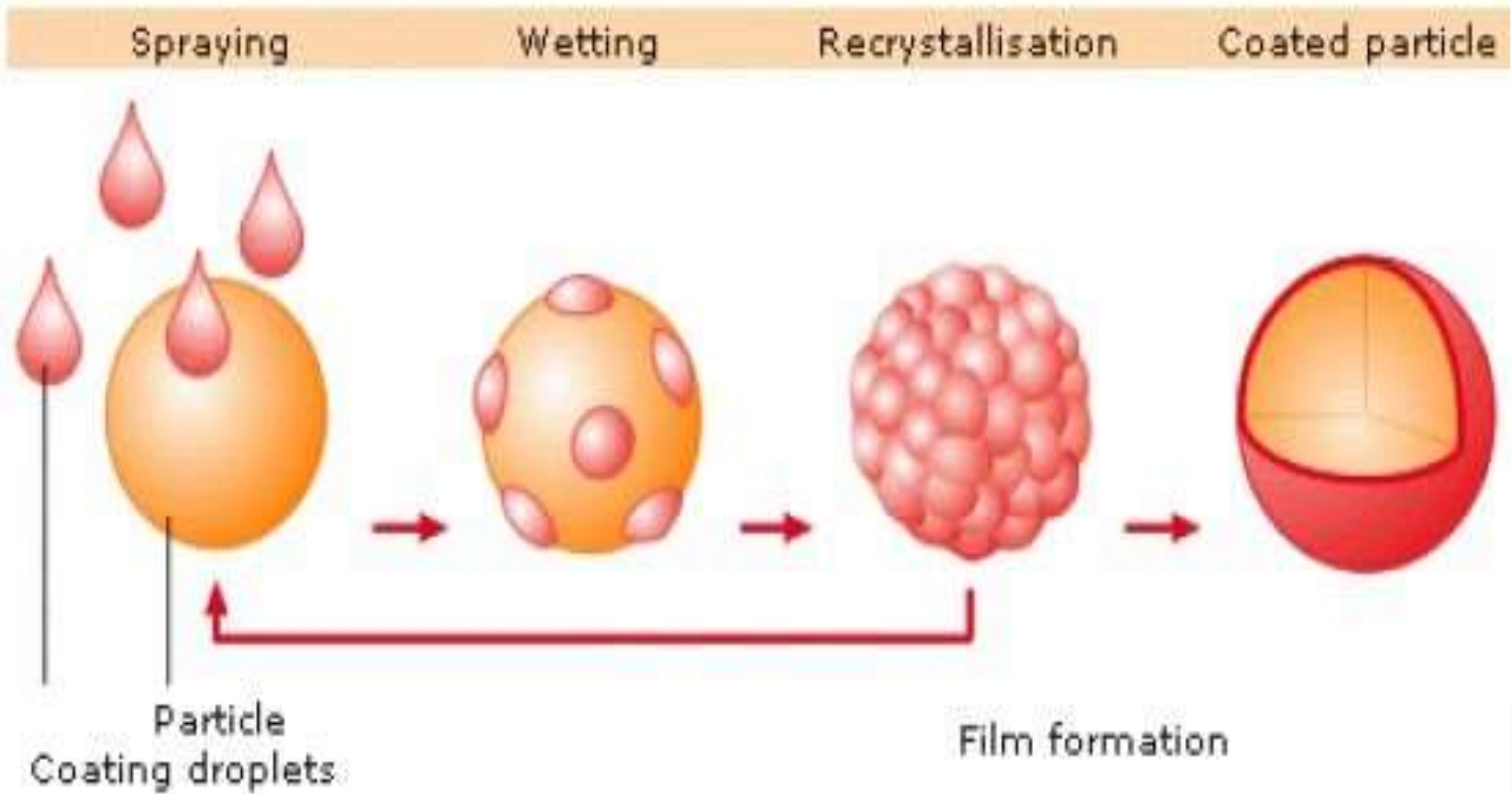


Types of Coating

- Sugar coating
- Film coating
- Enteric coating
- Controlled release coating
- Specialized coating
- ┌ Compressed coating
- ┌ Electrostatic coating
- ┌ Dip coating
- ┌ Vacuum film coating



Tablet Coating process



Sugar Coating

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SUGAR COATING



- ❑ Sugar coating is the most conventional multistep coating process.
- ❑ As the name suggests, this process involves application of sugar (sucrose) based coating solution to the tablets.
- ❑ It is carried out in coating pans having variable capacities & mounted at an angle of 40°
- ❑ Its use of labour is more, require a fair degree of skill.

Advantages of S.C.

- ⊕ cheap, safe coating material
- ⊕ cheap coating machine
- ⊕ good patient compliance
- ⊕ can be reprocessed
- ⊕ require less hardness core



Disadvantages of S.C

- ⊕ time consuming process.
- ⊕ high weight gain.
- ⊕ increase in packaging & shipping.
- ⊕ required trained personnel.
- ⊕ Imprinting problems.



Raw Materials for Sugar Coating

Sugar & it's Subtituents: Glucose, lactose, isomalt, sugar alcohols

Binders: Acacia, gelatin, PVP

Coloring agents: Water soluble (dyes), water insoluble (lakes)

Anti- Adherents: Talcum, colloidal silica

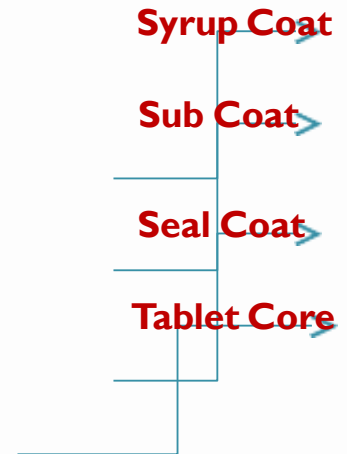
Fillers: CaCO_3 , CaSO_4 , starch, talcum, TiO_2

Polishing Agents: beeswax, carnauba wax, paraffin

Other agents: Flavouring agents, surfactants

Steps involved in Sugar Coating

- Sealing/Seal coating
- Sub-coating
- Syruping/Grossing/Smoothing
- Coloring Polishing/Finishing
- Printing
-



Steps involved in Sugar coating



SEALCOATING



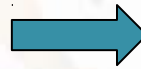
- to prevent water from coating solution
- to prevent migration from core
- to produce enteric coating (some cases)
- to reduce core abrasion

- **Sealing/Water proofing:** Provides a moisture barrier and harden the tablet surface.
- e.g. :Shellac, Zine, Cellulose acetate phthalate (CAP), Polyvinylacetate phthalate, Hydroxylpropylcellulose, Hydroxypropylmet hylcellulose etc

Steps involved in

Sugar coating

SUBCOATING



- to round off sharp edge of core
(smooth surface is not required)
- to provide a good substrate for
subsequent smoothing step

□ Generally two methods are used for subcoating:

- The application of gum based solution followed by dusting with powder and then drying. This routine is repeated until the desired shape is achieved.**
- The application of a suspension of dry powder in gum/sucrose solution followed by drying.**

Steps involved in

Sugar coating

Syruping / GROSSING / SMOOTHING



- to smooth the rough core surface.
- to provide a smooth base for color coat

Grossing/Smoothing: It is specifically for smoothing and filing the irregularity on the surface generated during subcoating. It also increases the tablet size to a predetermined dimension.

Steps involved in

Sugar coating

COLORING



- to achieve an evenly colored, smooth surface

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Steps involved in Sugar coating

POLISHING/FINISHING

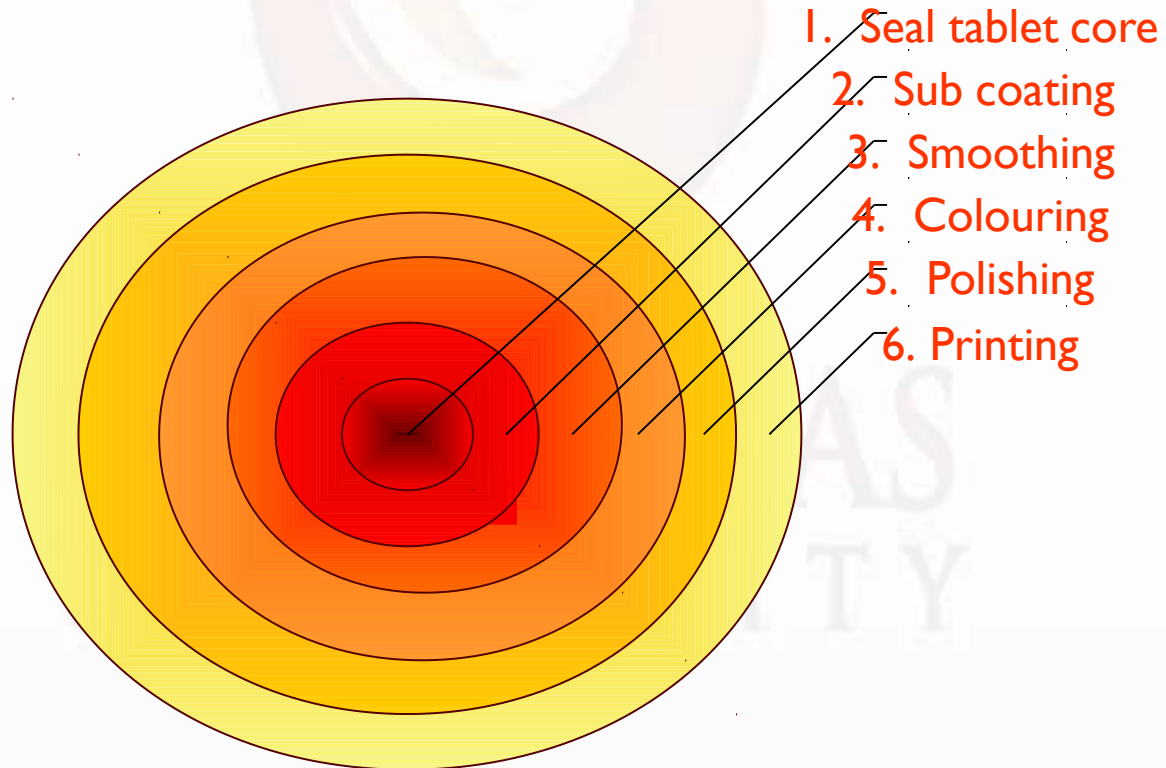


- to enhance gloss.
- to provide moisture protection.



Sugar Coating

- Traditionally sugar coatings formed the bulk of coated tablets but today film coatings are the more modern technology in tablet coating.
- **Description of tablets:** Smooth, rounded and polished to a high gloss.
- **Process:** **Multistage process** involving 6 separate operations.





FILM COATING

- Modern approach to coating
 - Tablets,
 - Capsules, Or
 - Pellets
- by surrounding them with a thin layer of polymeric material.



Raw Material For Film Coating

- 1. Polymers:**
- 2. Solvents:**
- 3. Plasticizers:**
- 4. Colorants:**

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FILM COATING

Process:

- Single stage process, which involves spraying a coating solution.
- The solution is sprayed onto a rotating tablet bed followed by drying, which facilitates the removal of the solvent leaving behind the deposition of thin film of coating materials around each tablet.

Enteric coating

The technique involved in enteric coating is protection of the tablet core from disintegration in the acidic environment of the stomach by employing pH sensitive polymer, which swell or solubilize in response to an increase in pH to release the drug.

Aims of Enteric protection:

- | To mask taste or odour
- | Protection of active ingredients, from the acidic environment of the stomach.
- | Protection from local irritation of the stomach mucosa.
- | Release of active ingredient in specific target area within gastrointestinal tract.

Formulations of coating solution: The constituents of coating solutions used for sugar coating are given below:

Seal coating	Sub coating	Syrup coating	Polishing soln.
Zein/Shellac	Gelatin	Colorant	Carnauba wax
Oleic acid	Acacia	Sub coating powder	(yellow)
Propylene glycol	Sugar cane powder	Cal. Carbonate	Bees wax
PEG 4000	Corn syrup	Cane sugar powder	(white)
Methylene chloride	Syrup	Corn starch	Paraffin wax
Alcohol	Distilled water	Syrup	Naphtha
		Distilled water	

Enteric coating polymers: Cellulose acetate phthalate, Acrylate polymers, Hydroxypropyl methyl cellulose phthalate, Polyvinyl acetate phthalate

Solvents used for coating: Ethanol, Methanol, Isopropanol, Chloroform, Acetone, Methylene chloride, Methylene ethyl ketone

COATING PANS

TYPES OF COATING PANS

1. CONVENTIONAL COATING PANS

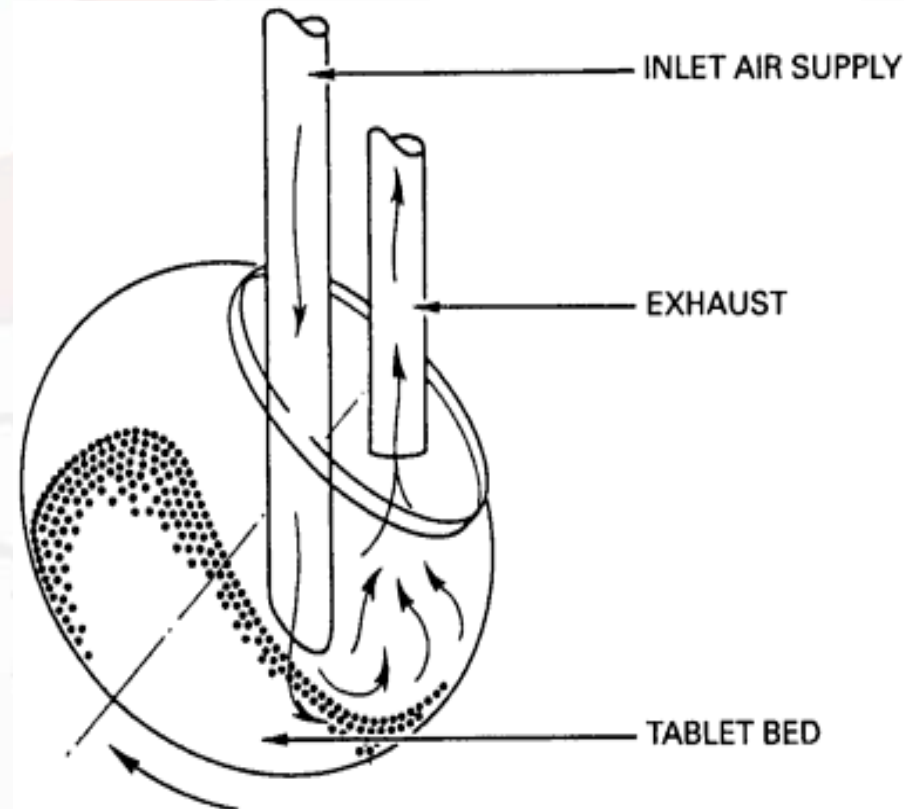
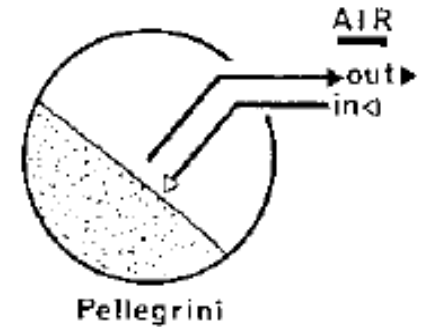
- A) PELLIGRINI PAN
- B) IMMERSION SWORD TYPE PAN
- C) IMMERSION TUBE TYPE PAN

2. PERFORATED COATING PANS

- A) ACCELA COTA PAN
- B) HI-COATER
- C) DRIA COATER
- D) GLATT PAN-COATING EQUIPMENT
- E) HUTTLIN BUTTERFLY PAN
- F) DUMOULIN IDA.X. COATING EQUIPMENT

1. STANDARD COATING PAN

- 1) Circular metal pan mounted at 40 degrees .
- 2) 8-60 inch diameter.
- 3) Rotated on its horizontal axis by a motor.
- 4) heated air is supplied by inlet air supply.
- 5) Exhaust by means of ducts.
- 6) coating soln are applied to tablets by ladling or spraying .
- 7) use of atomizing system to produce even distribution of coatings soln or suspension .



DRAW BACKS OF STANDARD COATING PAN

- 1) Mixing efficiency of tablets was poor.
- 2) Drying efficiency was low because much of drying took place on surface of the tablet bed only.
- 3) Improper balance b/w the introduced & exhausted air increased the chances of health hazards for the operator & risk of explosion when organic solvents were used in coating solution.


PELLIGRINI COATING PAN

- 1) Available in the range of 10-1000 kg batch.
- 2) Contains baffled pan & diffuser that distributes the drying air uniformly.
- 3) suitable only for sugar coating process but not for film coating due to limitations in drying capabilities.
- 4) Limitations was overcome by installing glatt immersion sword air handling system to improve drying efficiency.

2. Immersion sword system:

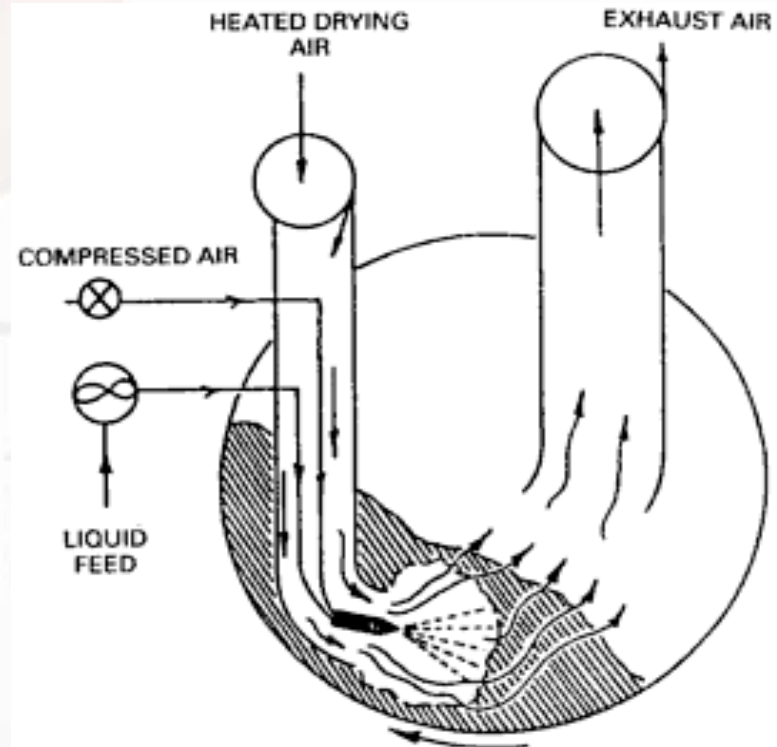
- Perforated metal sword device immersed in the tablet bed.
- Drying air is introduced through this device and flows upward from the sword through the tablet bed.

3. Immersion tube system:

- Tube immersed in the tablet bed.
 - Tube delivers the heated air.
 - In immersion tube system the coating solution is applied with the heated air from the immersed tube.
- 

IMMERSION TUBE COATING PAN

- 1) consists of long tube with a spray nozzle at its tip.
- 2) hot air gets delivered through this tube into tablet bed.
- 3) the drying air flows upward & exhausted by a conventional duct.
- 4) Relatively rapid processing times have been reported for both film & sugar coatings with this system.



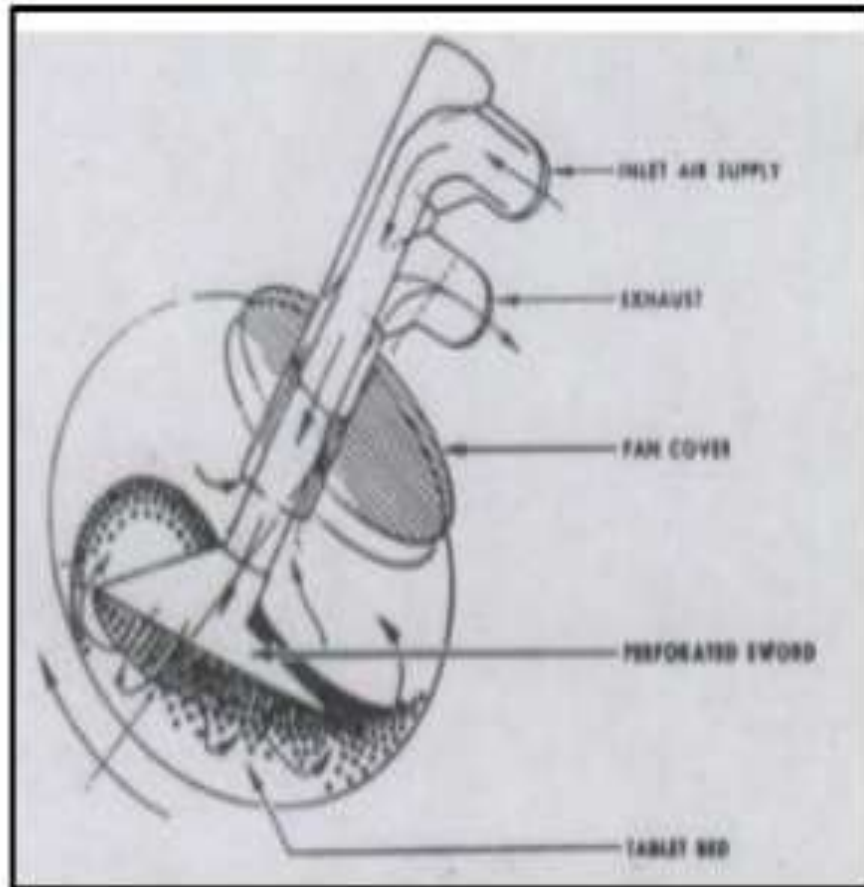


Fig 2: Immersion sword system

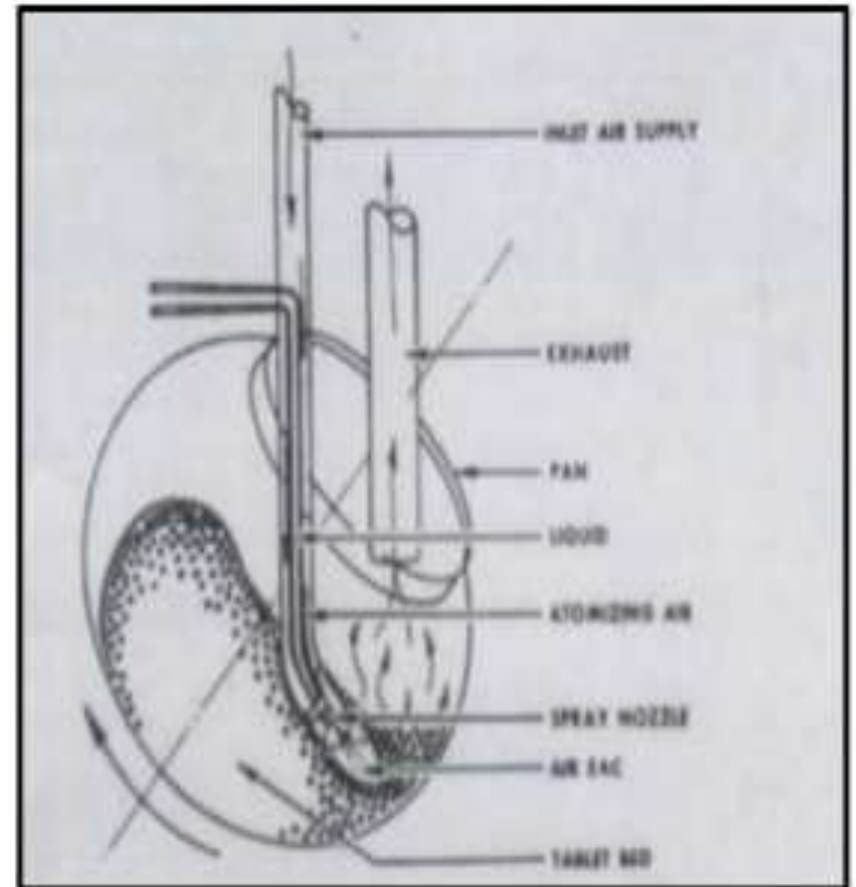
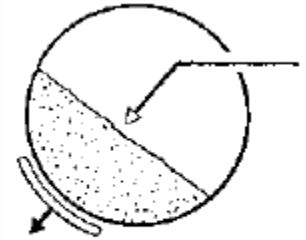


Fig 3: Immersion tube system

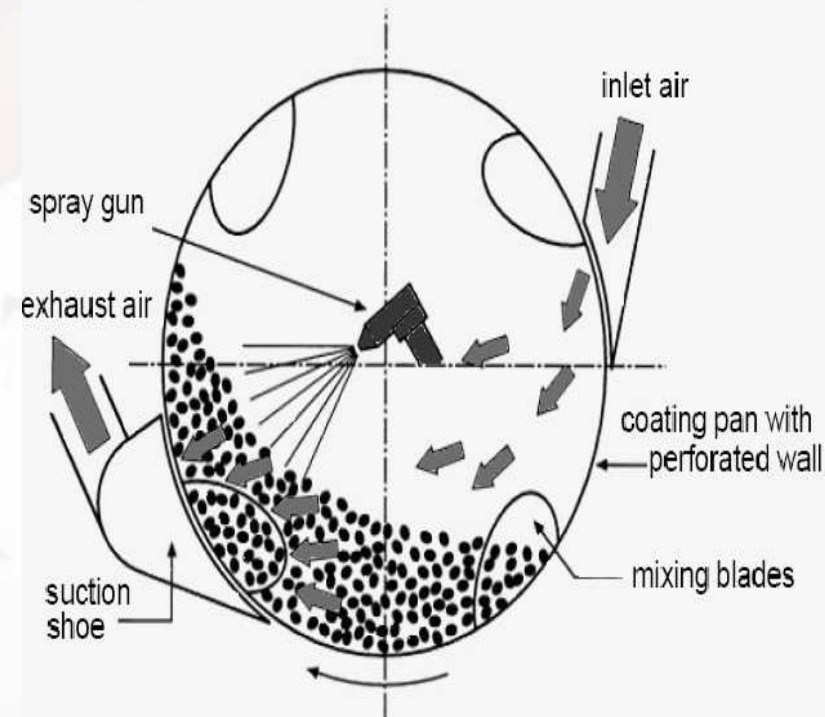
2. PERFORATED COATING PANS

ACCELA-COTA PAN

- 1) pan is fully perforated.
- 2) contains mixing blades.
- 3) inlet air is by a plenum in contact with the top of the pan.
- 4) air is exhausted by a plenum located below the pan.



Accela-Cota

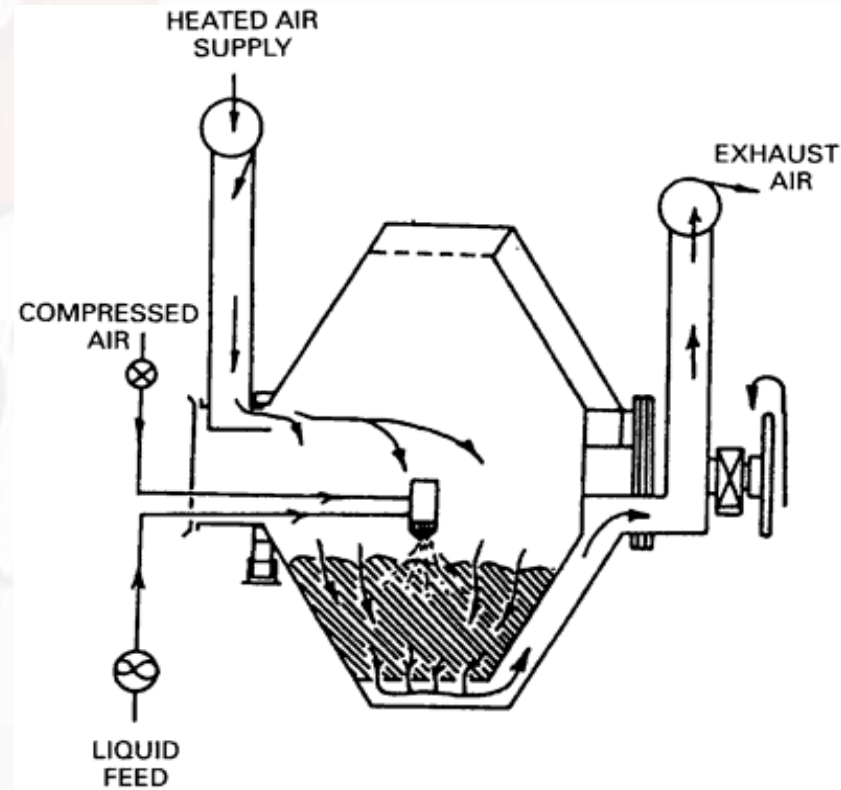
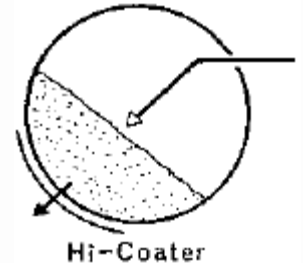


HI-COATER PAN

1) consists of four perforated segments which are perpendicular to each other.

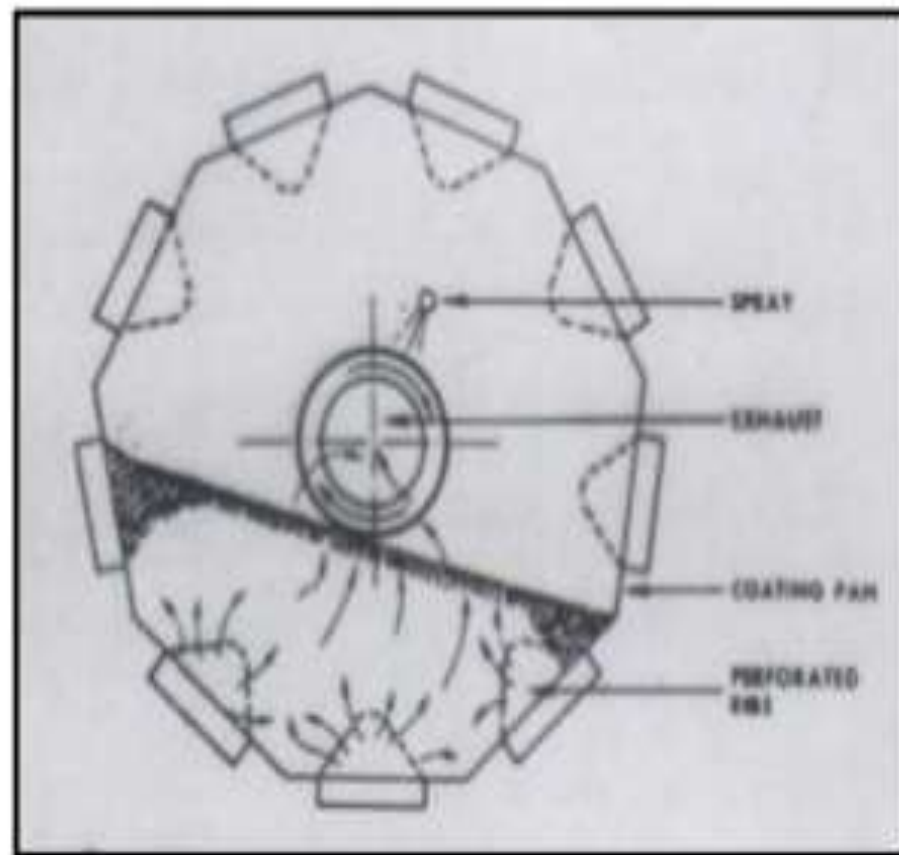
2) each of these perforations acts as an opening for air outlet which is fixed to the exterior of the pan surface.

3) drying air is introduced into pan through an opening located on inside periphery of top of the pan.




3. Dria coater

- Drying air enters through hollow perforated ribs, located on inside periphery of the drum.
- As the coating pan rotates, the ribs dip into the tablet bed and drying air passes up through
- Exhaust is from the back of pan.



Dria coater

C) Fluidized bed coater.

- ❖ Highly efficient drying systems
 - ❖ The airflow is controlled so that more air enters the centre column, causing the tablets to rise in the centre.
 - ❖ The movement of the tablets is upward through the centre of the chamber.
 - ❖ They then fall toward the chamber wall and move downward to re enter the air stream at the bottom of the chamber.
- 

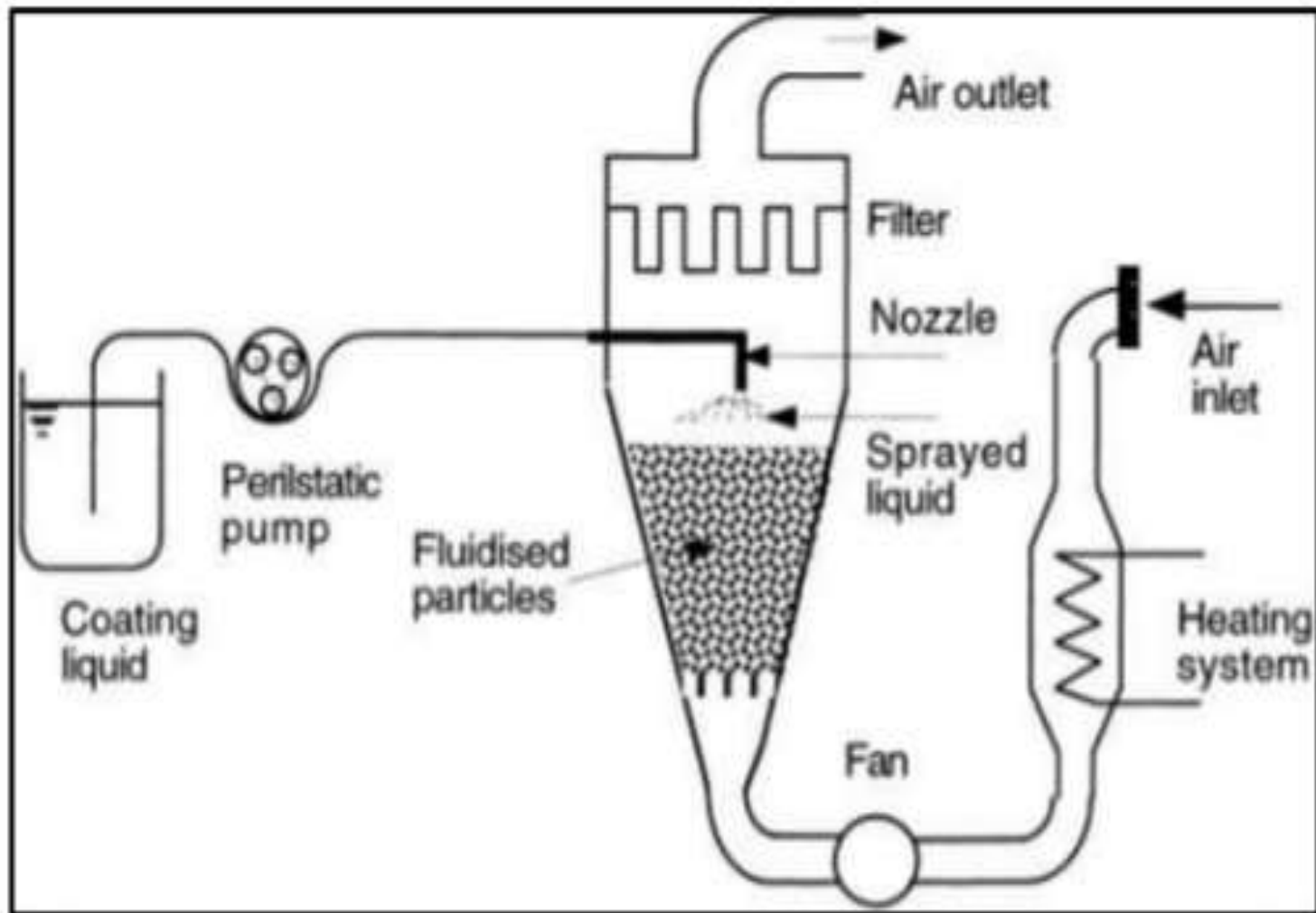


Fig: Fluidized bed coater

- ❖ Coating solutions are continuously applied from a spray nozzle located in the upper region of chamber.

- ❖ There are two types of systems to apply a finely divided spray of coating solution or suspensions onto tablets
 - a) High pressure, airless
 - b) Low pressure, air atomized

❑ **Airless spray system**

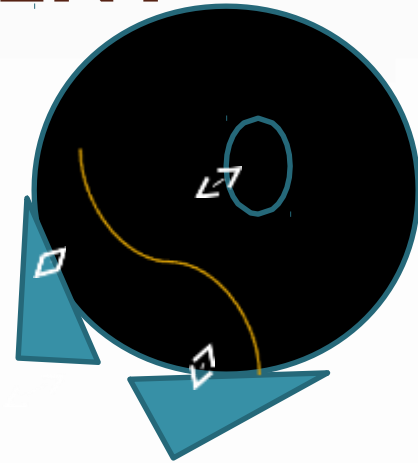
- Liquid is pumped at high pressure (250-3000 pounds per square inch gauge)
- through a small orifice (.009 inch to .020inch) in the fluid nozzle Which results in a finely divided spray.

❑ **Air - atomized system**

- Liquid is pumped through a somewhat large orifice (0.020 inch-0.060 inch in diameter) at relatively low pressure(5-50 psig)

GLATT PAN-COATING EQUIPMENT

- 1) similar to that of accelacota.
- 2) a divided air plenum located beneath the moving tablet bed enables air to be blown into or exhausted from the pan through either or both of the two sections.
- 3) in addition , another air plenum , connected to an opening above the door (similar to that in a hicoater) also allows air to be blown into or exhausted from the pan.
- 4) quite expensive.



FILM DEFECTS

S.NO	Tablet defects	Cause	Remedies
1	Blistering	Entrapment of gases in the film due to overheating during spraying.	Milder drying conditions are warranted in this case.
2	Chipping	Decrease in fluidizing air	Be careful not to over dry the tablets in the pre-heating stage.
3	Picking	It creates overly wet bed where adjacent tablets stick together and break apart	Increase in the drying air temperature and air volume
4	Twinning	Common problem	Increase the pan speed
5	Pitting	Temperature of the tablet core is greater than the melting point of the materials used in the formulation	Control of temperature of tablet core
6	Cratering	Coating solution penetrates the surface of the tablet	-----
7	Blooming	Mostly due to plasticizer	-----
8	Color variation	Alteration of the frequency and duration of the spray zone	A best way is to reformulate with different plasticizers
9	Cracking	Internal stress in the film exceeds tensile strength of the film	Use of high molecular weight polymer blends
10	Orange peeling	Inadequate spreading of the coating solution	Thinning the solution with additional solvent
11	Mottling	Degradation of the product	Prepare coating solution properly



Coating Defects

Coating Defects

CHIPPING

- Involves increased brittleness of the tablet.
- Causes :
 - High degree of attrition associated with the coating process like:
 - ┌ excessive use of fillers & pigments
 - ┌ low amount of polymers
- Remedy :
 - Increase hardness of the film by increasing the molecular weight grade of polymer.

Coating Defects

STICKING & PICKING

- Sticking involves sticking of the tablets with each other & with pan walls.
- Picking is the aftermath case of sticking involves adhering of some portion of coated layer to pan or to another tablet at the point of contact.

- Causes :

Higher rate of application of coating solution

Inefficient drying.

- Remedy :

Use optimum and efficient drying conditions.

Increase the inlet air temperature.

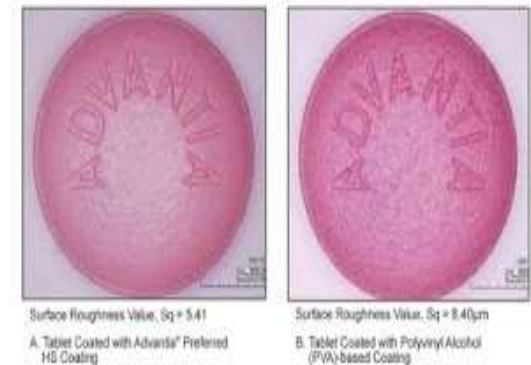
Decrease the rater of application of coating solution by increasing viscosity of coating solution.



Coating Defects

ROUGHNESS

- Involves presence of previously dried sprayed coating solution droplets onto the core.
- Causes :
 - # Drying of coating solution before reaching the surface of tablet during spraying.
 - # Excessive pigments concentration.
- Remedy :
 - # Moving the nozzle closer enough.
 - # Reducing the degree of atomization.



Coating Defects

- CRACKING

- • The coating cracks when the internal stress exceeds the tensile strength of tablets.

- Causes :

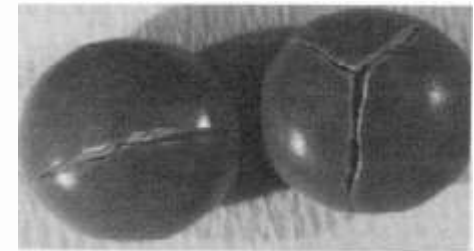
Absorption of moisture.

Internal stress relaxation after compaction.

Excessive coating material concentration.

- Remedy :

Adjusting the coating solution concentration.



Coating Defects



TWINNING

- Two or more tablets that sticking together.
- Causes :
 - Inefficient drying.
 - Higher rate of application of coating solution.
- Remedy :
 - Choosing appropriate shaped tablets.
 - Controlling the drying & rate of movement of pan.
 - Adjusting the coating solution concentration.

Coating Defects

BLOOMING/HAZING

- The polish of product to take on a fogged appearance.
- Causes :
 - # High temperature during formulation.
 - # Exposure to high humidity conditions.
- Remedy :
 - # Controlling humidity conditions.
 - # Formulation temperature monitoring.

Coating Defects

BRIDGING/FILLING

- Occurs in tablets consisting monogram or bisection.
- Coating shrink or pull away – Bridging
- Too much filling & thereby narrowing - Filling
- Causes :
 - improper application of the solution.
 - poor design of the tablet embossing.
 - high coating viscosity.
 - high percentage of solids in the solution.
 - improper atomization pressure.
- Remedy :
 - Control of spraying of coating solution.
 - Soft edged font for monogram.
 - Atomization control.
 - Concentration of coating material.



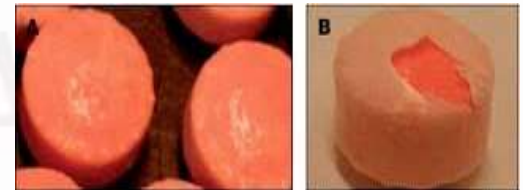
- BLISTERING

- • An un-smooth coated surface shows a number of uneven spots called blisters.
- Causes :
Effect of temperature on the strength, elasticity and adhesion of the coat.
- Remedy :
Use mild drying condition.

Coating Defects

ORANGE PEEL EFFECT

- Coating texture that resembles the surface of an orange.
- Before drying causes a bumpy or “orange-peel” effect on the coating.
- Causes :
 - # High atomization pressure in combination with spray rates.
 - # Too rapid drying.
 - # High solution viscosity.
- Remedy
 - # Thinning the solution with additional solvent.
 - # Controlling the drying procedures.



COLOUR VARIATION (MOTTLING)

- Variation in the proposed colour for coating.
- Causes :
 - # Improper mixing.
 - # Uneven spray pattern.
 - # In-sufficient coating.
 - # Unevenness of the surface of the sub coat.
- Remedy
 - # Using lake dyes.
 - # Go for geometric mixing.
 - # Use mild drying conditions.



References

- Shah A. Coating Tablet Defects: The Cause and The Remedies, 2011, <http://vikramthermoblogspot.in/2011/06picking-and-sticking.html>.
- <https://www.rroij.com/open-access/techniques-of-tablet-coating-concepts-and-advancements-a-comprehensive-review.php?aid=34923>
- The science and practice of pharmacy by Remington, Volume I, Page no: 905 to 916.