- 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

Coating

by

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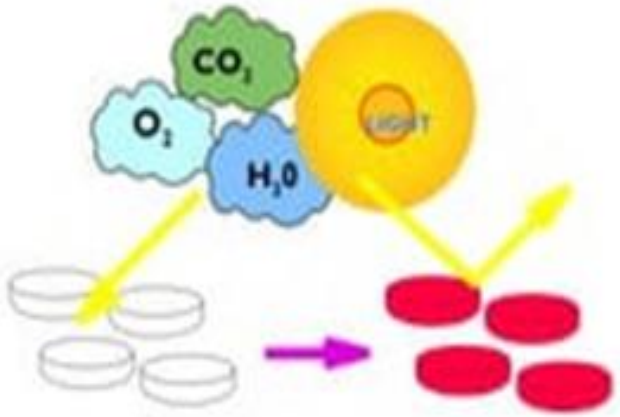
Why To Coat?

Coating for Marketing

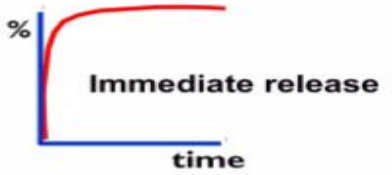
- Allows the product to stand out بالتميزfrom the competition
- To Improves pharmaceutical appearance by using colors and contrasting printing.
- Colour and tablet shape for branding and trademark

Coating for Product Stability

- To protect the medicinal agent against destructive exposure to air and/or humidity.



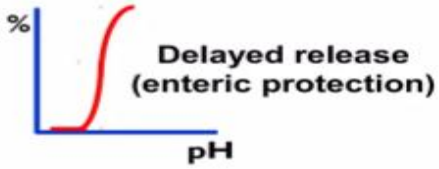
Why To Coat?



Coating for Release

❑ to provide special characteristics of drug release

- No functional coat.
- Provide release of drug at various GI sites depending on pH. (protect drug from gastric 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 (mask the unpleasant taste)

→ Odour (Mask unpleasant odour)

➢Properties of Tablet to be coated

- Tablet to be coated must has the proper physical characteristics like spherical shape and uniform surface, which allow tablet to be covered more uniformly in short time.

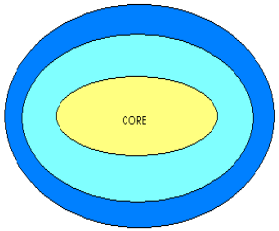
- Tablet may be compressed harder than uncoated one to be able to withstand the additional coating processing.

- Tablet must be free from dust to be uniformly smooth .

- To tolerate attrition of tablets during coating process they must be resistant to abrasion and chipping.

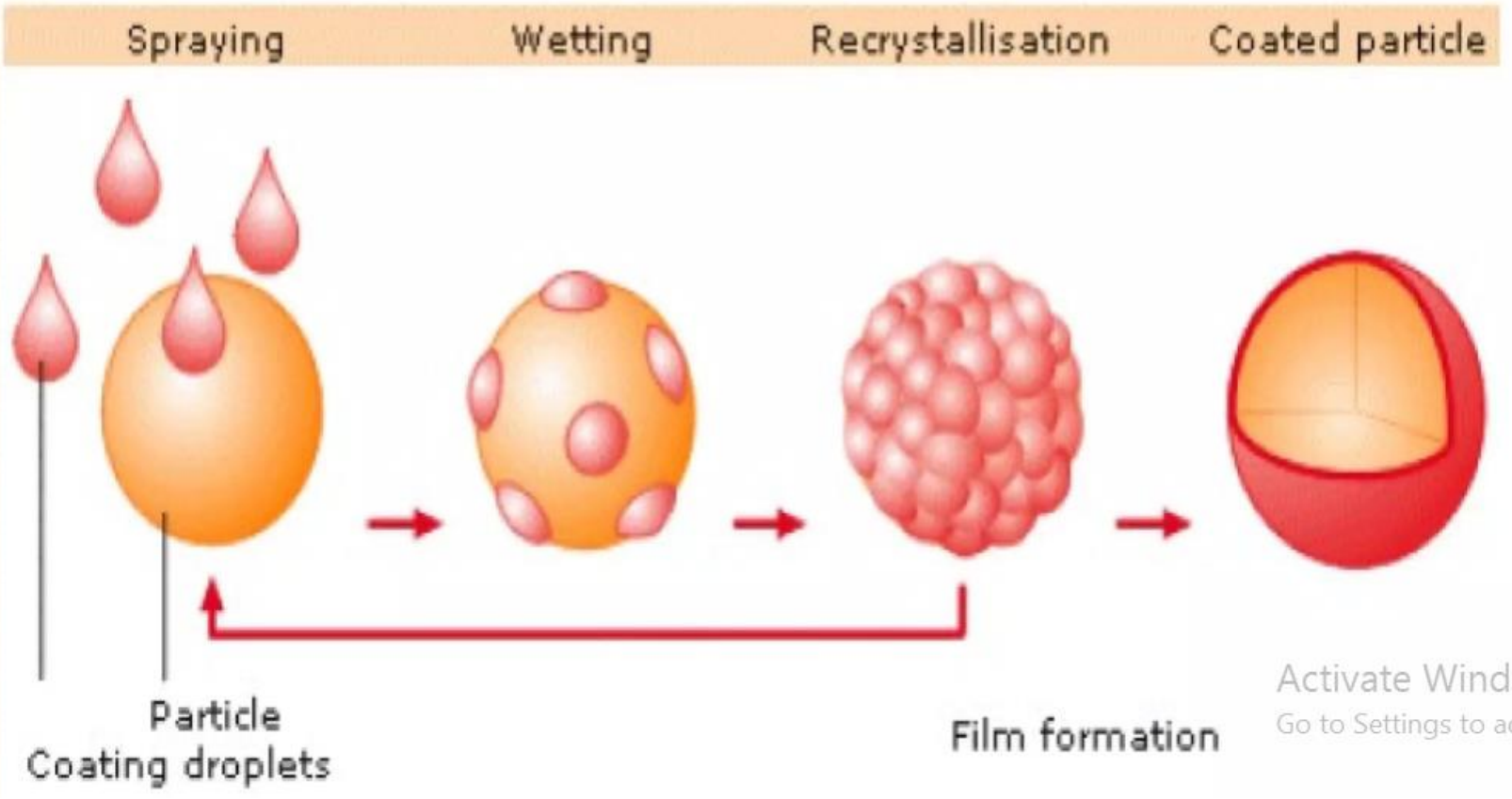
- As the tablet surfaces that are brittle and soften in presence of heat or effected by coating composition and tend to become rough in the early stages of coating process are unacceptable for film coating.

❑ The main types of coatings



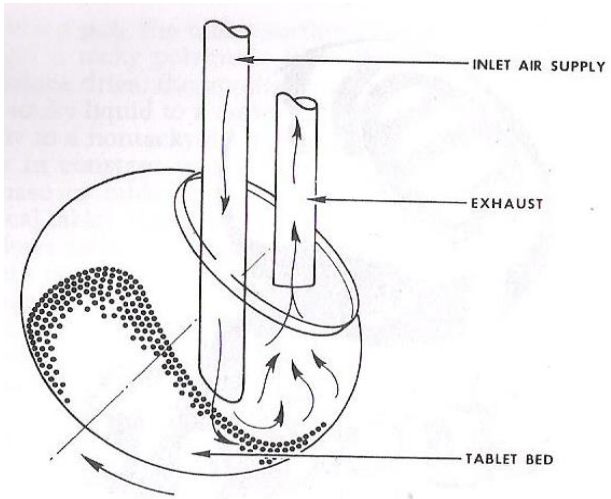
1. **Sugar coating**
2. **Film coating**
3. **Enteric coating**
4. **Compression coating**
5. **Air suspension coating**

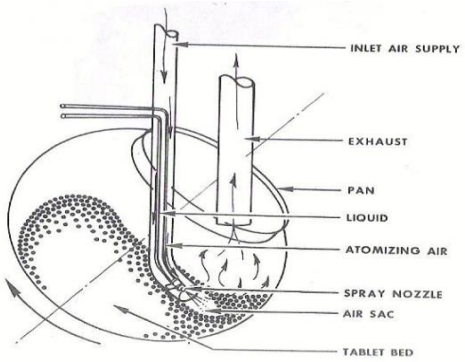
Tablet Coating process



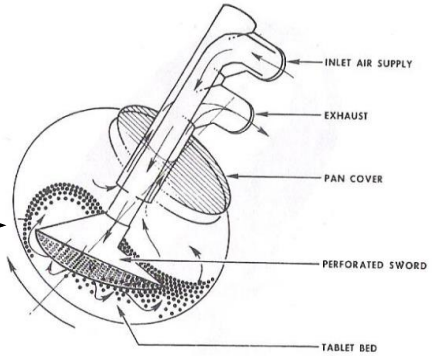
STANDARD COATING PAN

Standard Coating Pan

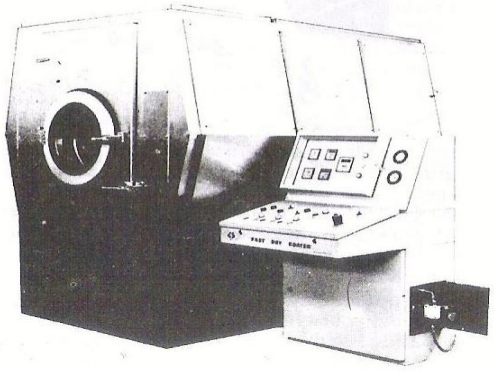




Immersion-tube system



Glatt Immersion sword system



Pellegrini pan system

1.SUGAR COATING

- Commercially, sugar coating form the bulk of coated tablet but today film coating are the more modern technology in tablet coating.
- As the name suggests, this process involves application of sugar (sucrose) based coating solution with color to the tablets for several times to give uniform and elegant film.
- Its use of labour is more, require a fair degree of skill.
- The coat thickness is 0.4 to 0.5 mm.
- The maximum coat weigh is approximately equal to the weight of uncoated tablet.
- The tablet having deep convex surfaces with thin rounded edges are suitable for sugar coating.
- **Description of tablets:** Smooth, rounded and polished to a high gloss.

1.SUGAR COATING

Advantages

1. It prevents unpleasant odour .
2. Give sweet taste to tablet by masking bitter taste.
3. Highly elegant and glossed tablets are obtained.
4. cheap, safe coating material

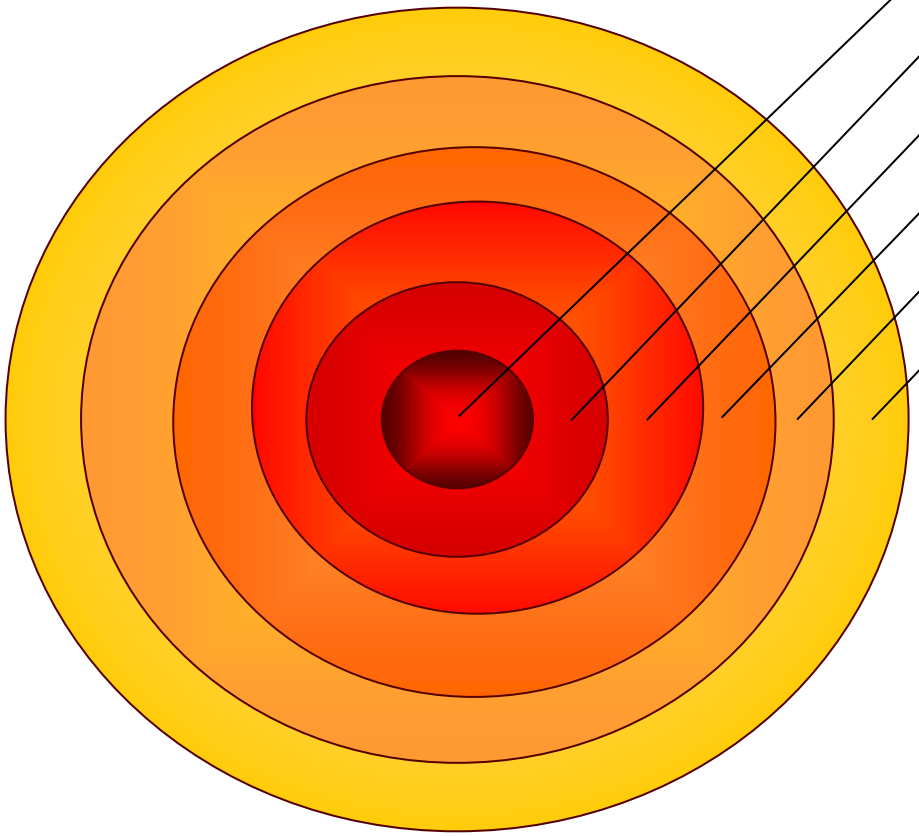
Disadvantages

1. time consuming process.
2. high weight gain.
3. increase in packaging & shipping.
4. 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

❑ Sugar coating involves the following steps :.



1. Seal tablet core
2. Sub coating
3. Smoothing
4. Colouring
5. Polishing
6. Printing

Multistage process

1. **Sealing tablet core-** application of a water impermeable polymer such as Shellac, cellulose acetate phthalate and polyvinyl acetate phthalate, which protects the core from moisture, increasing its shelf life.

2. **Sub coating** -by adding bulking agents such as calcium carbonate or talc in combination with sucrose solution.

3. **Smoothing process** -remove rough layers formed in step 2 with the application of sucrose syrup.

4. **Colouring** - for aesthetic purposes often titanium based pigments are included.

5. **Polishing** - effectively polished to give characteristic shine, commonly using beeswax, carnauba wax.

6. **Printing** -indelible لا يمحى ink for characterisation.

SEAL COATING

- This involved the application of one or more coats of a waterproofing substance in the form of alcoholic spray, such as pharmaceutical Shellac (traditionally) or synthetic polymers.

WHY Sealing?

Sugar-coatings are aqueous formulations which allow water to penetrate directly into the tablet core and thus potentially affecting product stability and possibly causing premature tablet disintegration. So

→ to prevent water from coating the solution

→ enables SC product to exhibit modified-release pattern (extended release or delayed "enteric"- release characteristics) (some cases)

→ to reduce core abrasion

1- Sealing

➢ Operation

1. The tablet free dust are placed in coating pan.
2. A small amount of shellac solution is applied to the rolling tablets.
3. Mixing the rolling tablet by hand to ensure distribution of shellac solution.
4. After 5 min turn on the cold air to dry the shellac solution.
5. After 10 min the tablet are dry.
6. Addition of seconded coat solution (= to half of first coat) then dried.

SUBCOATING

- Large quantities of sugar-coatings are usually applied to the tablet core (typically increasing the tablet weight by (50- 100%)
- Antiadherents e.g. Talc may be added after partial drying to prevent sticking of the tablets together.

WHY?

- In order to round off the sharp edges of tablet Core (smooth surface is not required)
- build the tablet to the desired shape to provide a good substrate for subsequent smoothing step.

- Medium subcoating syrup (Acacia 2.25/ Gelatin 2.25/ sucrose 57.25/ water 38.25).
- Medium subcoating powder (Calcium carbonate 35/ Kaolin 16/ Talc 25/ Sucrose 20/ Acacia 4).
- Tablet may require from 9 to 30 coats.

➢ Operation

1. The gelatin syrup at 60 ° C is added to the preheated tablets in a rotating coating pan
2. Stir the tablet by hand to distribute the solution.
3. Dry the gelatin syrup (tablet beginning to form a ball).
4. Subcoating powder is sprinkled immediately in to the coating pan until no wet tablet show and the tablets roll freely.
5. Turn on the warm air until the tablets are dry (15 min for small batches).
6. Turn off the warm air, and subcoating procedure is repeated until the tablet are nicely shaped and coated.

GROSSING/SMOOTHING

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

→ using smoothing syrup (Sugar 60/ distilled water 40%).

→Tablet may require from 5to 25coats.

➢ Operation

1. Smoothing syrup solution at 60 ° C is added to a rotating tablets in a clean and dust free coating pan
2. After 5-10 min (when the tablet appear dull and roll freely), the warm air is turned on and still open for about 20 min utile the tablets becomes dry.
3. Smoothing procedure is repeated until the coating is smooth.

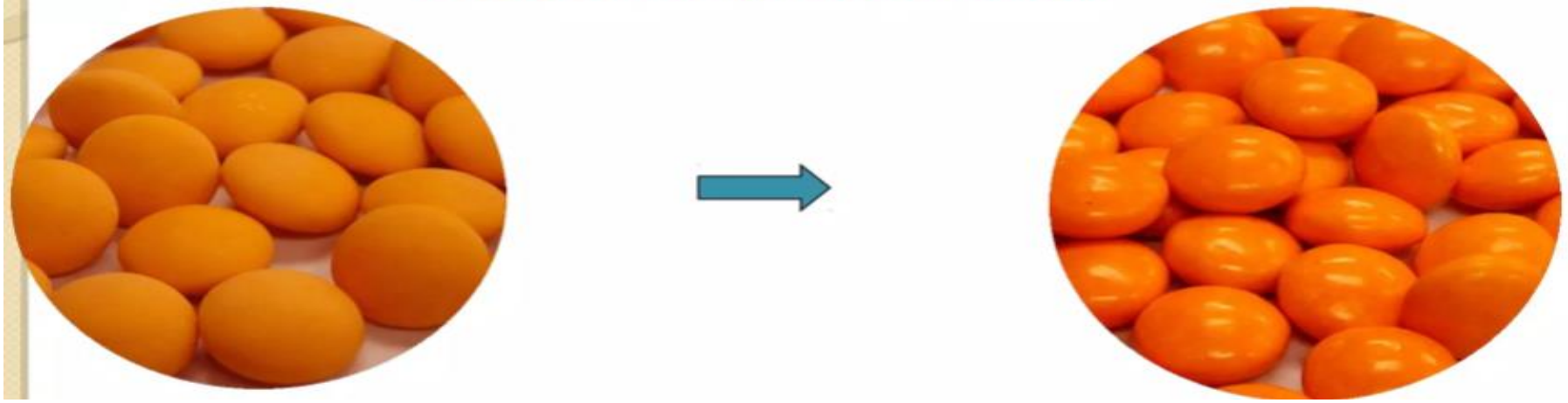
COLORING

- to achieve an evenly colored
- Color coating usually consist of thin sucrose syrup (Sugar 60/ distilled water 40%) containing color materials (certified water-soluble dye).
- A stock coloring syrup may contain dye from 0.1 to 0.6%.

➢ Operation.

1. Smoothing syrup solution containing dye is added to a rotating tablets in a clean pan deprived of any residue from previous operation.
2. The syrup is colored lightly in the beginning of the operation (1:15 dilution of the stock syrup, dye = 0.005-0.04%) and after several coats have been applied, several coats of highly colored syrup are applied. (The slow development of color prevents mottling of the coat).
3. The opening of the coating pan is covered with a cloth , then it is rotated manually by hand every 10-15 min with slow drying during 2 h until a very smooth finish is formed

POLISHING/FINISHING



- It is a final coating step, is application of a thin layer of a glossy wax solution mixture (bees wax 90/ carnauba wax 10 dissolved in warm petroleum benzene) to

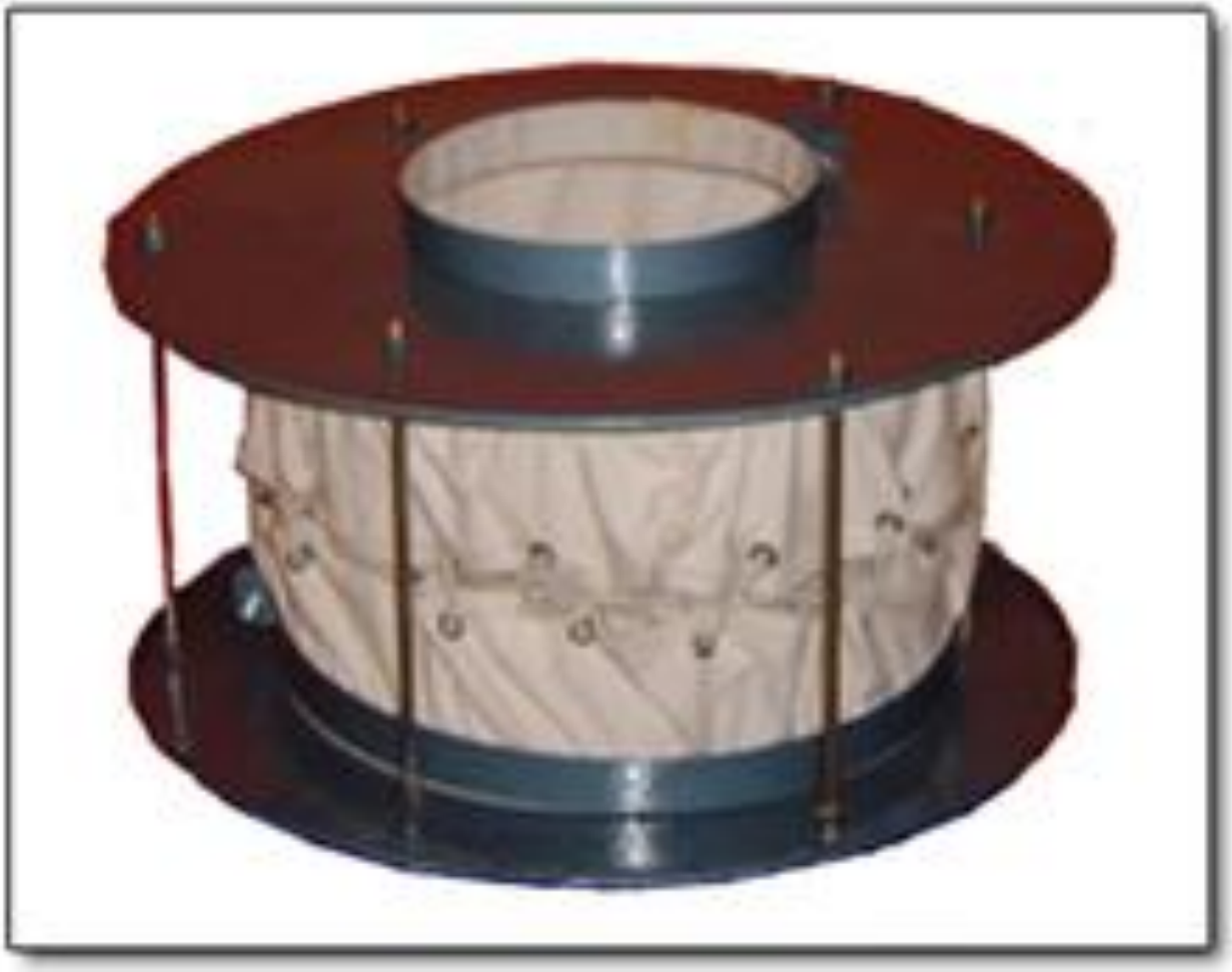
→ give a glossy finish appearance of tablet.

→ to provide moisture protection.

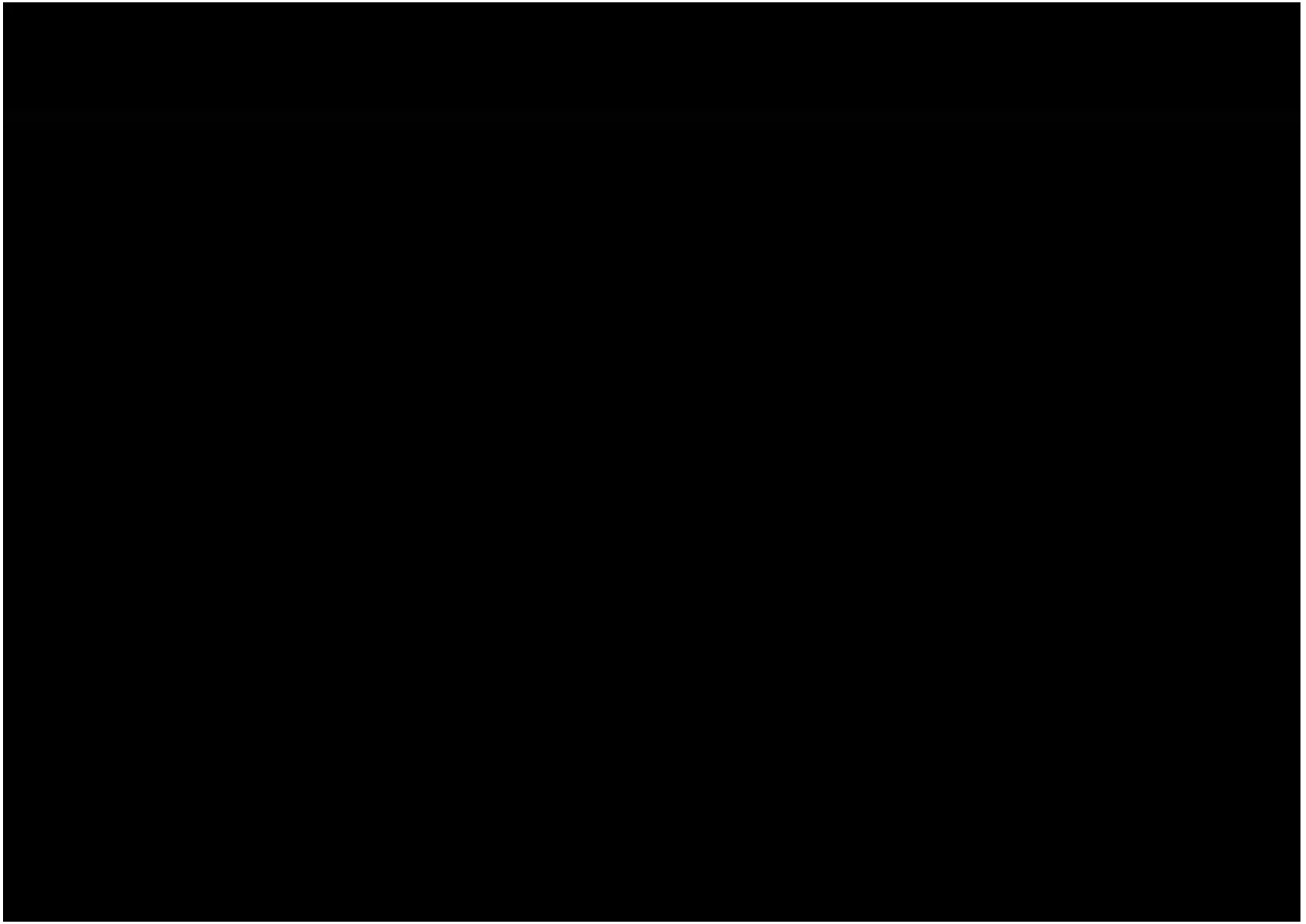
➢ **Operation.**

1. A warm polishing solution is added to the tablets in a clean pan then the pan is rotated until the solvent has been evaporated

The polishing mixture may be dusted on a tablets as a solid which is picked up by the rotating tablet



POLISHING



❑ Example of sugar coated tablets

Brufen®

- Available in 200mg and 400mg

Dusphaston®

- Dydrogesterone
- (white)

Dusptalin®

- Mebeverine hydrochloride 100mg Round, white, sugar coated

Cataflam ®

- Available in 25 and 50 mg

Film Coating

- Modern coating approach to reduce sugar coating process time and the need for operator skills.
- Modern approach to coating tablets, capsules, or pellets by surrounding them with a thin layer of polymeric material without significant change in tablet weight or size.

❑ Tablet appearance

- Retains shape of original core
- Small weight increase of 2-3% due to coating material
- logo or ‘break lines’ possible

Film Coating

❑ Process:

Single stage process, which involves spraying a coating solution containing the following;

1.Polymer (Film former)

2.Solvent

3.Plasticizer

- 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.

→ Can be automated e.g. **Dria Coat pan.**

→ Easy training operation

→ Single stage process

→ Easily adaptable for controlled release allows for functional coatings.

Film Coating

❑ Advantages

1. Produce tablets in a single step process in relatively short period of time.
2. Process enables functional coatings to be incorporated into the dosage form.

❑ Disadvantages

1. There are environmental and safety implications of using organic solvent as well as their financial expense.

❑ Types of film coating

A. Immediate release

B. Modified release

1.Polymer

- Polymer provide the main structure (an basic physical and chemical properties of coating).
- Viscosity of polymer is very important especially in aqueous coating to minimize the water conc. To short the process and decrease exposure of drug to moisture. (Vis ≥ 500 cip, difficult in atomization.

❖ **Immediate release coating polymer,** e.g. HPMC

- It readily soluble in aqueous media and form film with good mechanical properties (flexibility, strength and adhesion to core tablet).

❖ **Modified release coating polymer,** e.g. EC and Eudragit

- They dissolved in organic solvent or dispersed in aqueous media.

2.Plasticizers

- Plasticizers are generally added to film coating formulations to modify the physical properties of the polymer to make it more flexible. One important property is their ability to decrease film brittleness with age.
- Non volatile.

Examples of plasticizers are:

1. **polyols**, such as polyethylene glycol 400
2. **organic esters**, such as diethyl phthalate
3. **oils/glycerides**, such as fractionated coconut oil or castor oil.

- In general, only water-miscible plasticizers can be used for aqueous-based spray systems.

3.Colourants

1. Enhance product appearance and quality
2. Provide product identification.
3. Protect tablet from light and moisture.

- Any permitted colourants in a film coat formula are invariably water-insoluble colours (pigments). Pigments have certain advantages over water-soluble colours: they tend to be more chemically stable towards light, provide better opacity and covering power, and optimize the impermeability of a given film to water vapour.

Examples of colourants are:

- iron oxide pigments
- titanium dioxide
- aluminum Lakes.

4.Solvents

- Modern techniques now rely on Water-Ethanol as a polymer solvent because of the significant drawbacks that readily became apparent with the use of organic solvents.

❑ Requirement of solvent

1. Either dissolve or disperse the polymer.
2. Inert, colorless, odorless and inflammable.
3. Rapid drying rate.
4. safe

➢ Film coating solution

- ✓Hydroxypropyl methylcellulose 0.3 gm.
- ✓Propylene glycol 0.1 gm.
- ✓Ethyl alcohol 40 ml
- ✓Methylene chloride 100 ml

- ✓Methylene chloride added to the solvent to reduce fire hazard.

Examples of Film coated tablet

Primperan®

- Metoclopramide
- White
- Available in 10 mg

Cialis®

- Taldenafil
- (yellow)
- Available in 20 mg

Brufen 600®

- Ibubrfen
- 600mg elongated, white, film coated

Difference between Film coating & sugar coating

Film coating

Tablet appearance

- ✓ Retains shape of original core
- ✓ Small weight increase of 2-3% due to coating material
- ✓ logo or ‘break lines’ possible

Process

- ✓ Can be automated e.g. **Accela Cota**
- ✓ Easy training operation
- ✓ Single stage process
- ✓ Easily adaptable for controlled release allows for functional coatings.

Sugar coating

Tablet appearance

- ✓ Rounded with high degree of polish
- ✓ Larger weight increase 30-50% due to coating material
- ✓ Logo or ‘break lines’ are possible

Process

- ✓ Difficult to automated e.g. traditional coating pan
- ✓ Considerable training operation required
- ✓ Multistage process
- ✓ Not able to be used for controlled release apart from enteric coating.

Types of coating pans

1.Conventional coating pans

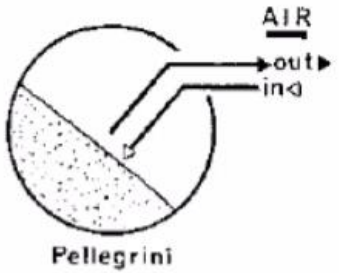
- pelligrini pana
- immersion sword type pan
- immersion tube type

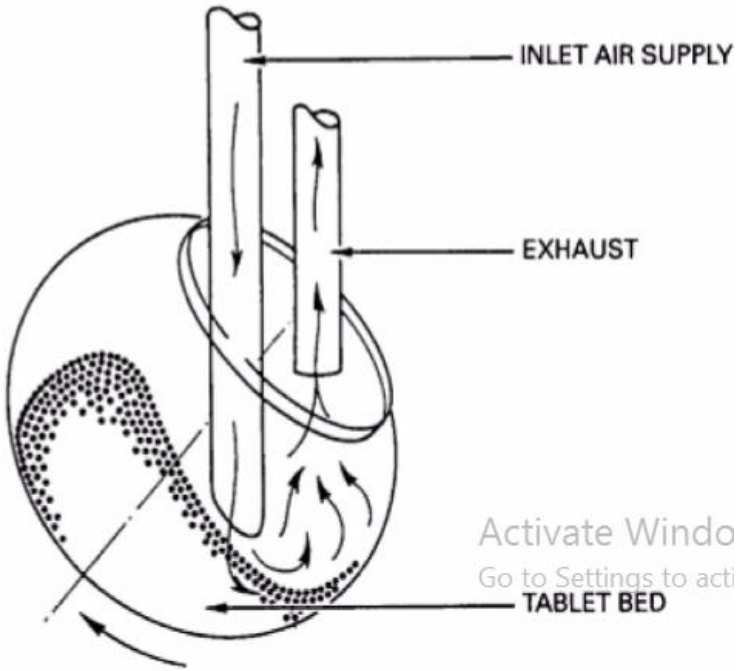
2.Perforated coating pans

- accela cota pana
- hi-coater
- dria coater

1. STANDARD COATING PAN

1) Circular metal pan mounted at 40 degrees .
2) 8-60 inch diameter.
3) Rotated on its horizantal 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 coatins soln or suspension .





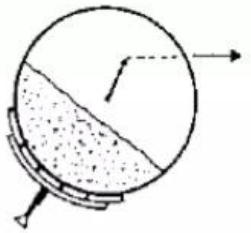
DRAW BACKS OF STANDARD COATING PAN

1) Mixing efficiency of tablets was poor.

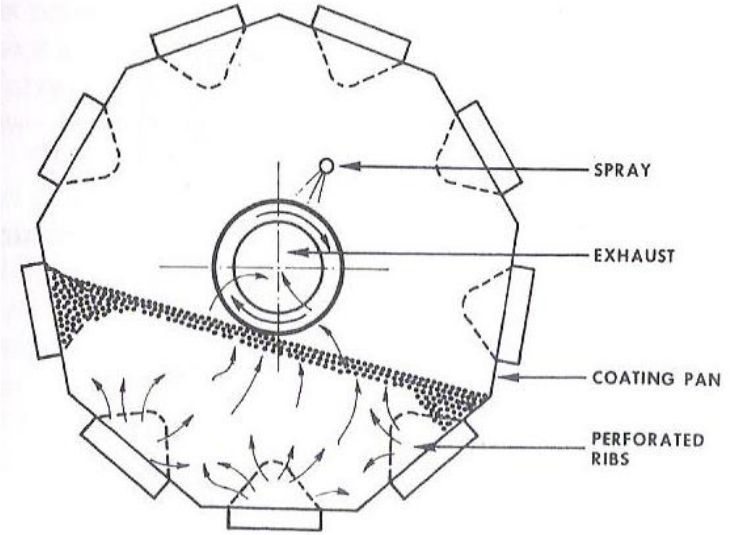
2) Drying efficiency was low because much of drying took place on surface of the tablet bed only.

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.

DRIA COATER

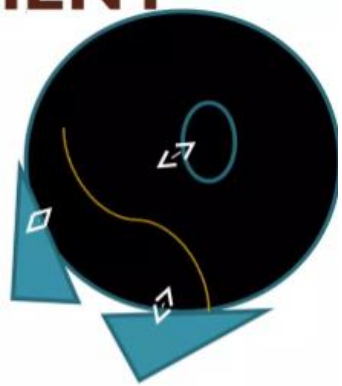

Driacoater

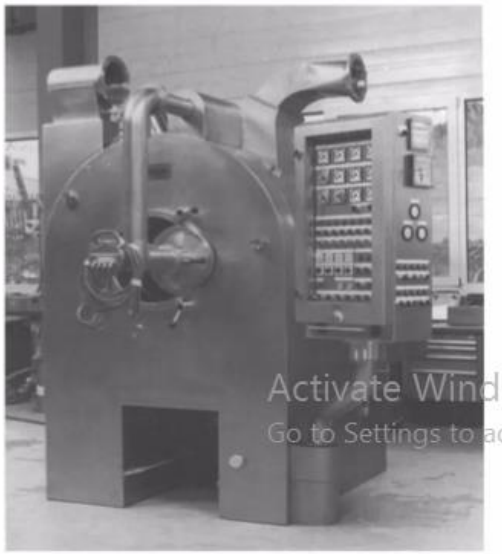
1) introduces drying air through hallow perforated buffles located on inside periphery of drum.
2) exhaust is from back of the pan.
3) different air flows
   - **a)direct flow:** air in at the top(through perforated baffles) and exhausted through baffles located beneath tablet bed.
   - **b)reverse flow A:** air in through baffles located beneath tablet bed and exhausted via baffles at top of pan.
   - **c)reverse flow B:** air in through baffles located beneath tablet bed,and exhausted via plenum connected to opening at back of pan.



GLATT PAN-COATING EQUIPMENT

1) similar to that of accela-cota.
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.





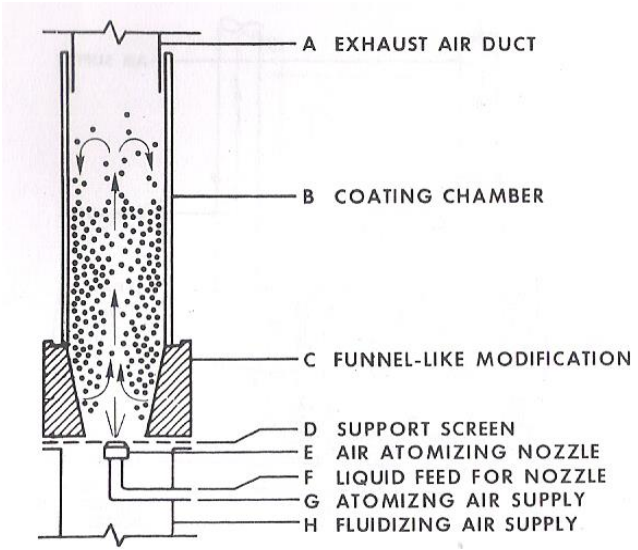

Glatt®

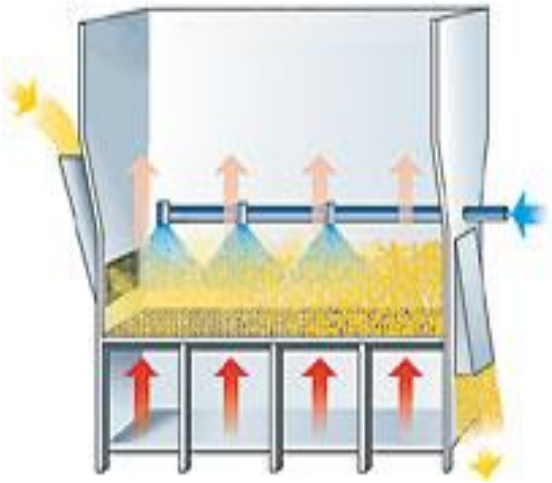
➢ Operation

1. As the coating pan rotate, the rips dip in to the tablet bed and drying air passes up through and fluidize the tablet.
2. Exhaust is from the back of the pan.
3. Coating solution is applied to surface of the rotating bed of the tablet through the nozzle in side the drum.

➢ It is an efficient drying system with high coating capacity automated for both sugar and film coating

Fluidized bed coater systems

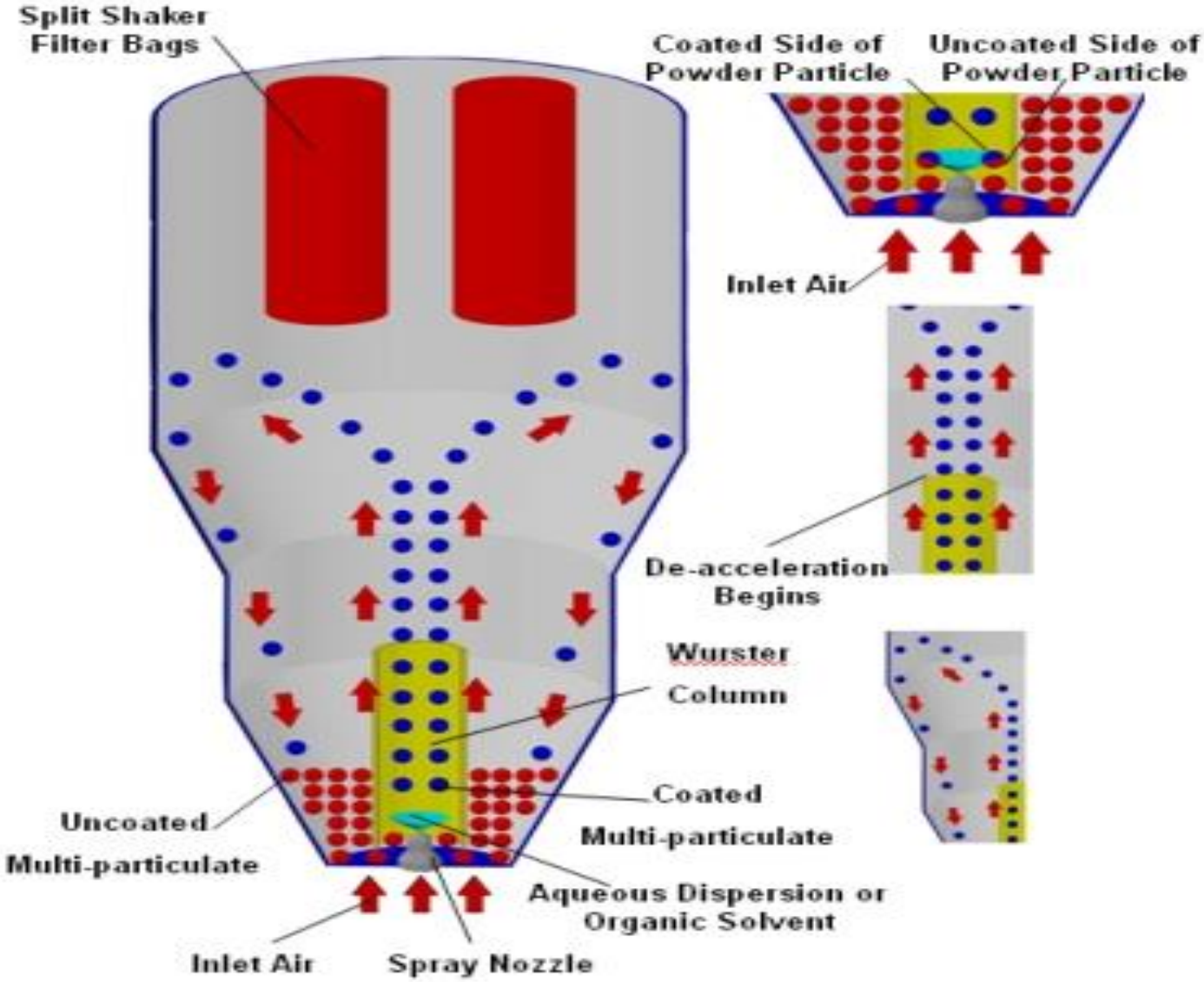


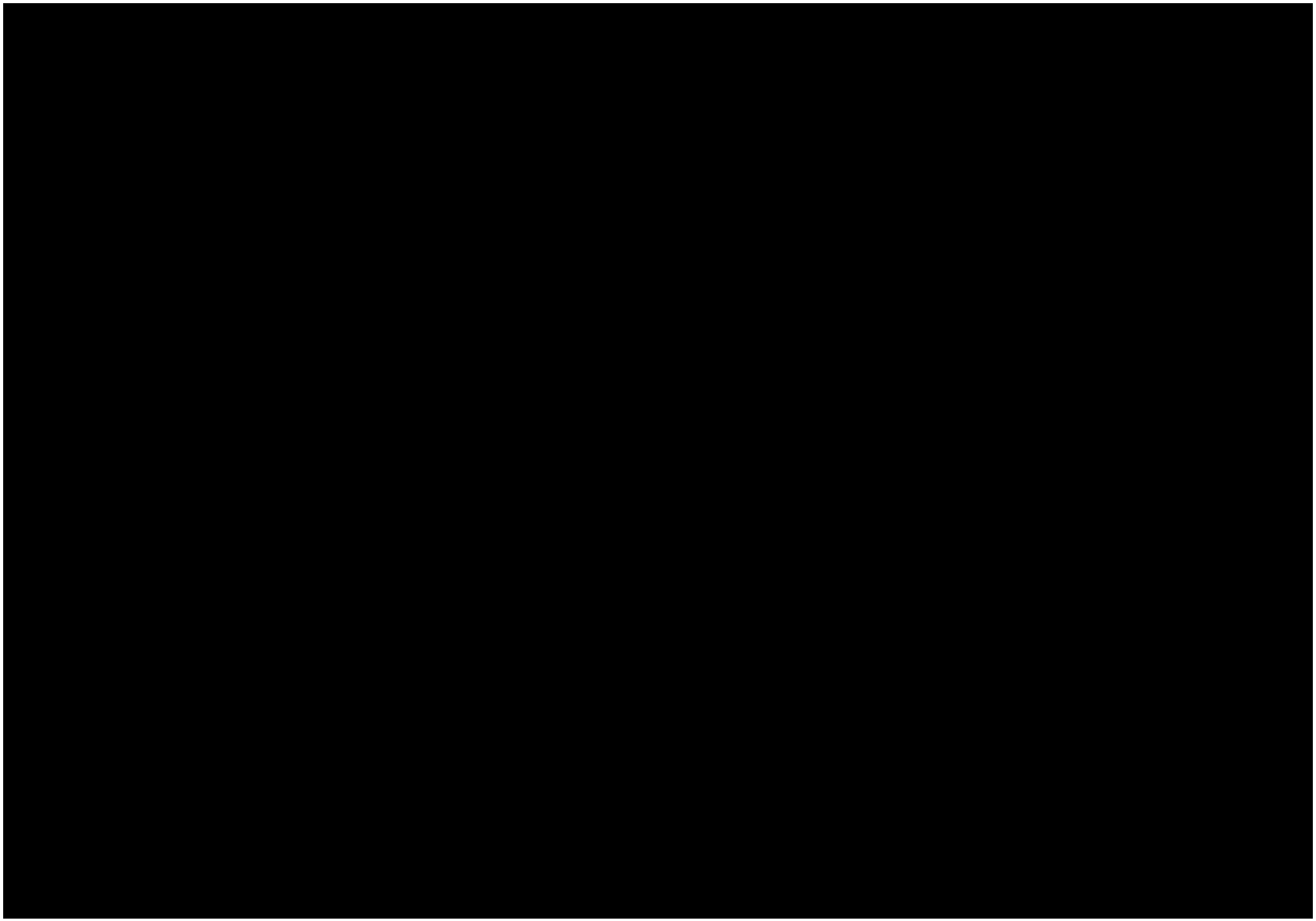


- Fluid bed processing involves drying and coating of particulate material.
- Tablet core to be coated by fluidized bed must be hard enough to be withstand the coating operation

➢ Operation

1. Up word flow of dry air from the bottom nozzle of column chamber cause fluidization of tablet and move it to the center of the column.
2. The tablet fall toward the chamber wall and move down to re enter the air system at the bottom of chamber.
3. Spray the coating solution continuously by spray nozzle located at the bottom of the chamber.
4. Open the warm air to dry the coating solution.


Split Shaker
Filter Bags
Coated Side of
Powder Particle
Uncoated Side of
Powder Particle
Inlet Air
De-acceleration
Begins
Wurster
Column
Coated
Multi-particulate
Uncoated
Multi-particulate
Aqueous Dispersion or
Organic Solvent
Inlet Air
Spray Nozzle



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 :

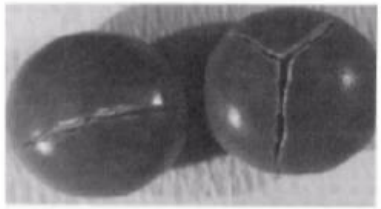
  # Moving the nozzle closer enough.

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.

Coating Defects

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

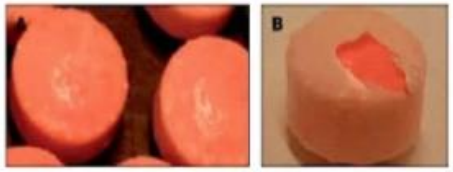
- Coating texture that resembles the surface of an orange.
- Before drying causes a bumpy or "orange-peel" effect or the coating.

- 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.

Coating Defects

COLOUR VARIATION

- 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.

Quiz

Give the scientific term that is described by each of the following sentences

1. Tablet allows delivery of therapeutic agents at different rates from single tablet.
2. long-acting sterile tablets designed to provide continuous release of drugs, often over a period of months or a year.
3. Tablet excipient that is added to improve powder flowability.
4. Polyol diluents specially used for chewable tablets due to its sweetness.
5. Disintegrant act by swelling in contact with gastric fluids and exert sufficient mechanical pressure within the tablet.

Term	Scientific term
1	
2	
3	
4	
5	