Tablet Coating

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TABLET COATING

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- ✓ **OBJECTIVES**
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TABLET COATING

- Tablet coating is the last critical step in the tablet production cycle.

- It is the phenomenon of application of coating to the tablet.

OBJECTIVES OF TABLET COATING

- Mask the odour, taste or color of the drug.
- Provides physical and chemical protection for drug.
- Controls the release of drug from the tablet.
- Protects the drug from gastric environment of stomach in case of acid sensitive drug.
- Avoids chemical incompatibility.
- Improves pharmaceutical elegance by using colors and contrasting printing.

COMPONENTS CONSIDERED IN TABLET COATING

- **Tablet Properties- Shape, tolerance, Surface area**

- **Coating process -**

A. **Coating equipment**
B. **Coating parameters**
C. **Facility & ancillary equipment**
D. **Automation of coating process**

- **Coating composition which involves polymers, color ,plasticizer ,solvent.**

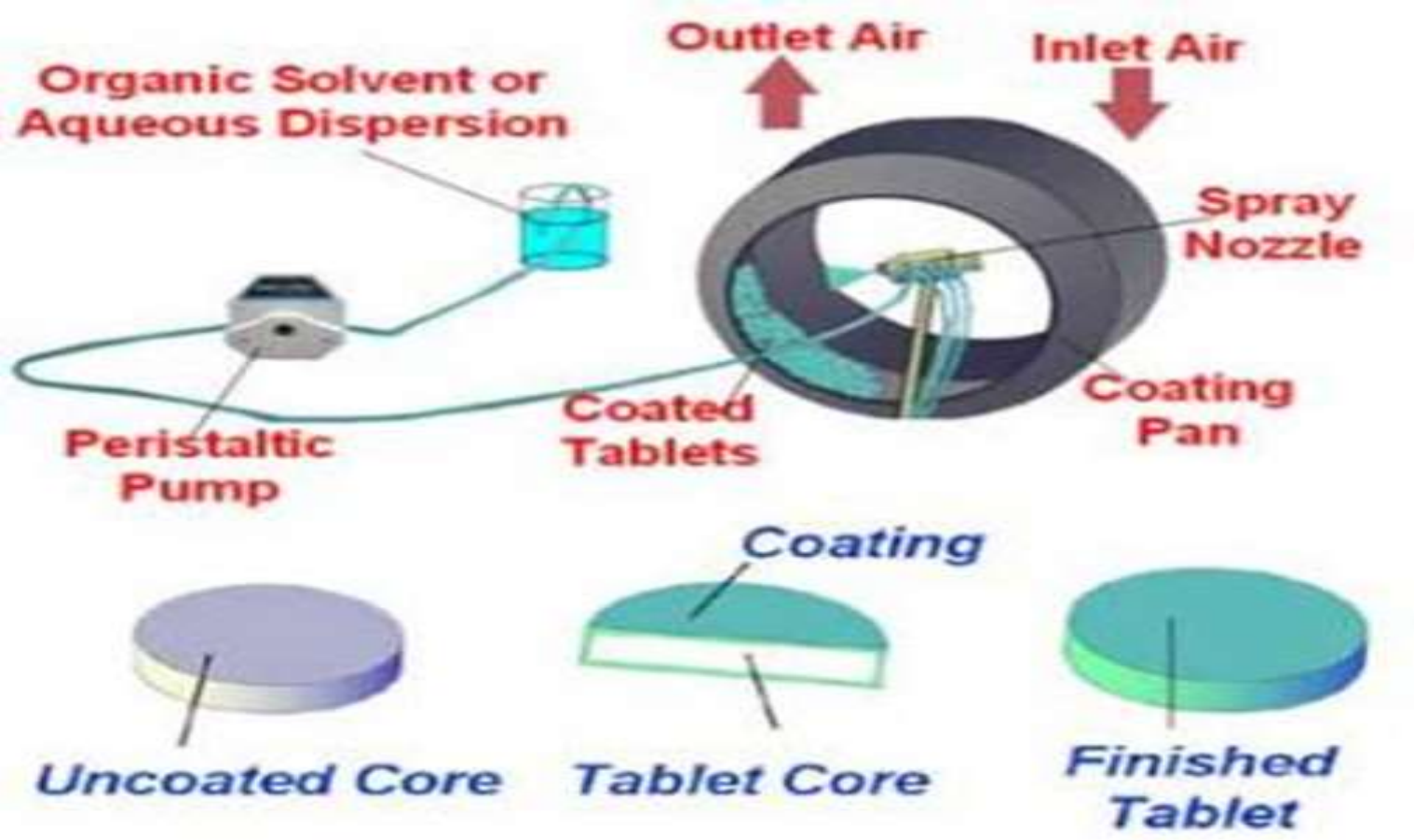
TABLET PROPERTIES

- Tablet to be coated must posses the proper physical characteristics like spherical shape and uniform surface.

- 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.

Tablet Coating Process

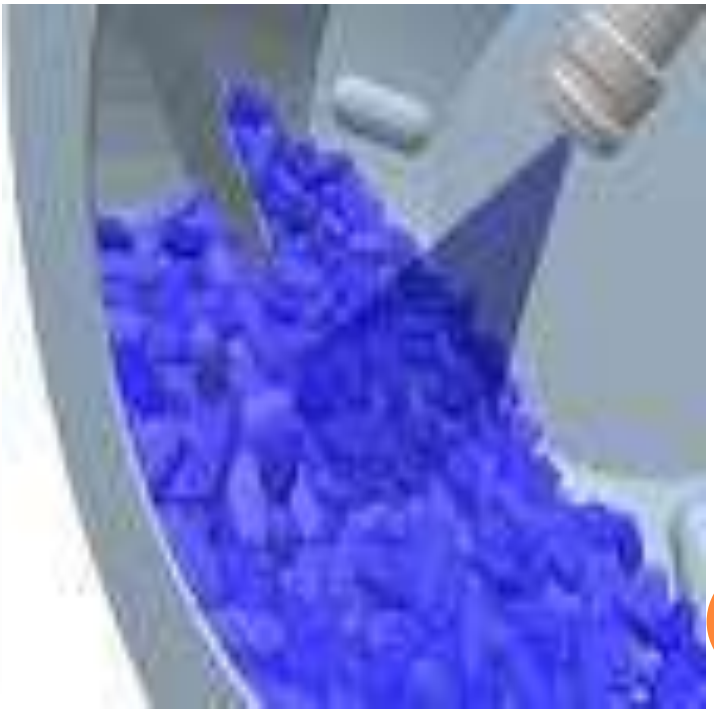


Wetting and Adherence

Accumulation and Partial Drying

Spreading

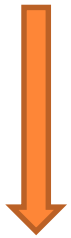
Coalescence and Cohesion



COATING PROCESS

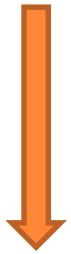
Tablet coating is accomplished by the movement of tablets in Perpendicular or vertical direction to the application of the coating composition

COATING COMPOSITION



IS APPLIED TO

MOVING BED OF TABLETS



HEATED AIR IS INTRODUCED

EVAPORATION OF THE SOLVENT

A. EQUIPMENTS

- **The equipments used for the tablet coating are :-**

I. **Standard coating pan**

I. **Perforated coating pan**

II. **Fluidized bed coater**

STANDARD COATING PAN

1. STANDARD COATING PAN

- It is also known as conventional pan system
- Circular metal pan(mounted angularly on a stand)
- 8-60 inches in diameter
- Rotated on its horizontal axis by a motor
- Heated air is directed into the pan & on to the tablet bed surface and is exhausted by means of ducts through the front of the pan

- **Coating solution are applied to the tablets by ladling or spraying the material on to the rotating tablet bed.**

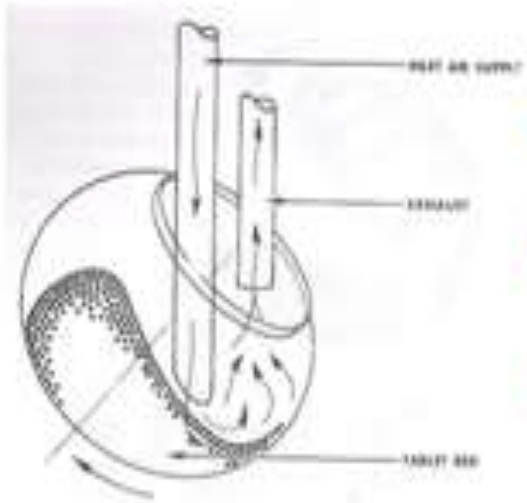
❖ *Use of spraying systems-*

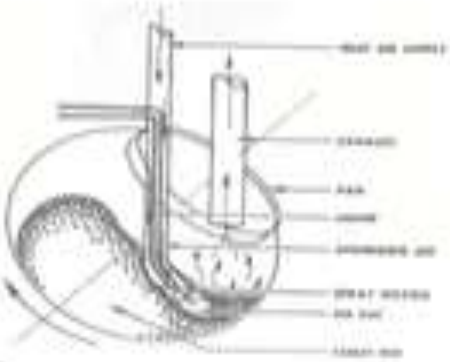
- **Produces a faster, more even distribution of the solution or suspension.**
- **Reduces drying time between solution application in sugar coating .**
- **Allows continuous application of the solution in film coating.**

In standard coating pan ,the drying efficiency is improved by:-

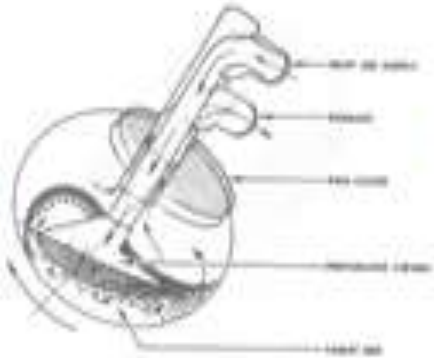
- Pellegrini pan
- The immersion sword
- Immersion tube systems

Standard Coating Pan





Immersion-tube system



Glatt Immersion sword system

Pellegrini pan system

- Pellegrini pan-

✓ Baffled pan

✓ Diffuser(distributes the drying air uniformly over the tablet bed surface).

- 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.

- 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

11. PERFORATED PAN SYSTEMS-

II. PERFORATED PAN SYSTEMS-

- Perforated or partially perforated drum.
- Rotated on its horizontal axis in an enclosed housing.
- The coting solution is applied to the surface of the rotating bed of tablets through spraying nozzles, which are present inside the drum.
- Perforated pan coaters are efficient drying systems with high coating capacity.

PERFORATED PAN SYSTEM HAS-

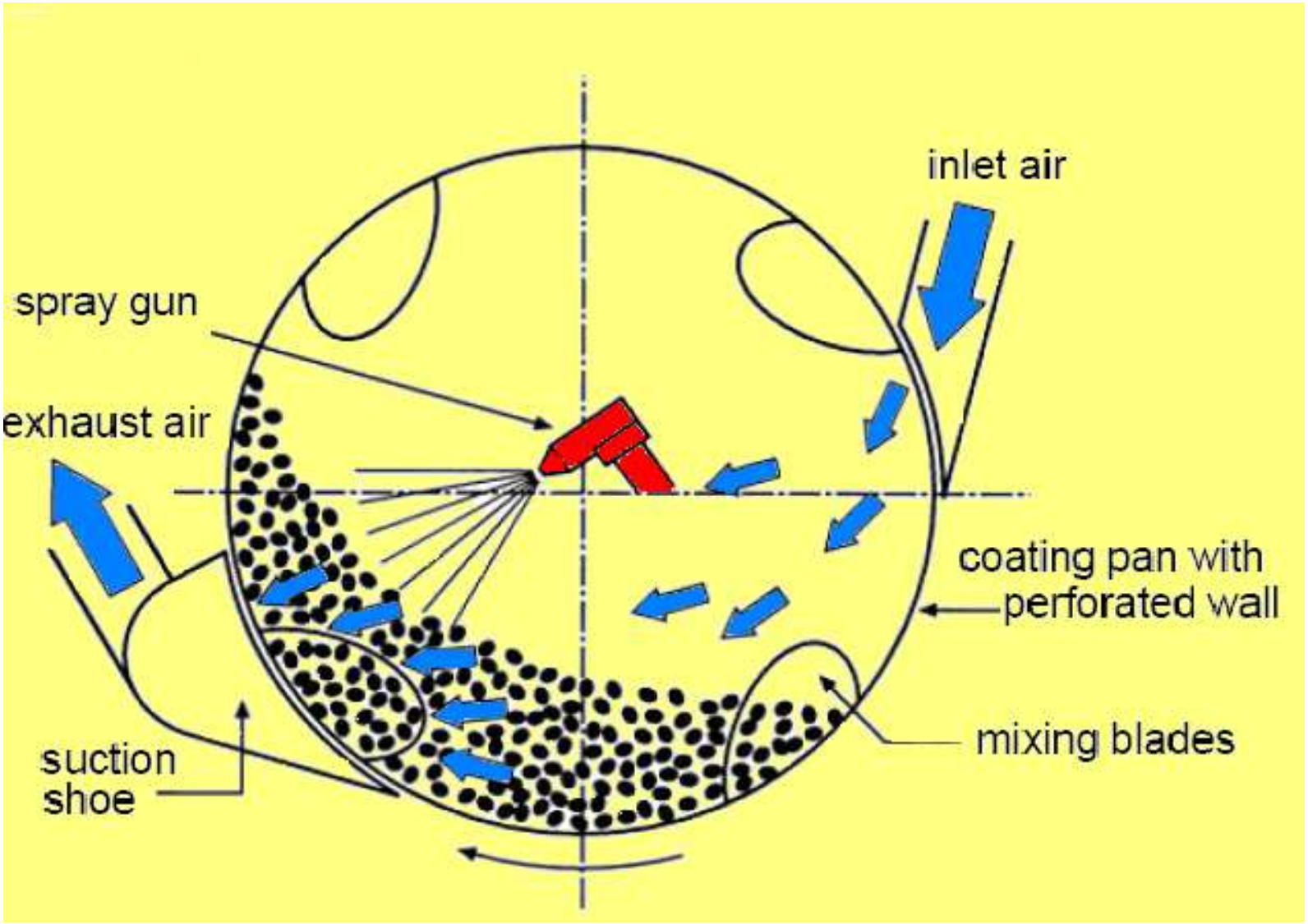
$- Accela-cota system

$- Hi coater system

$- Dria coater pan

$- Glatt coater

ACCELA -COTA


inlet air
spray gun
exhaust air
coating pan with
perforated wall
mixing blades
suction
shoe

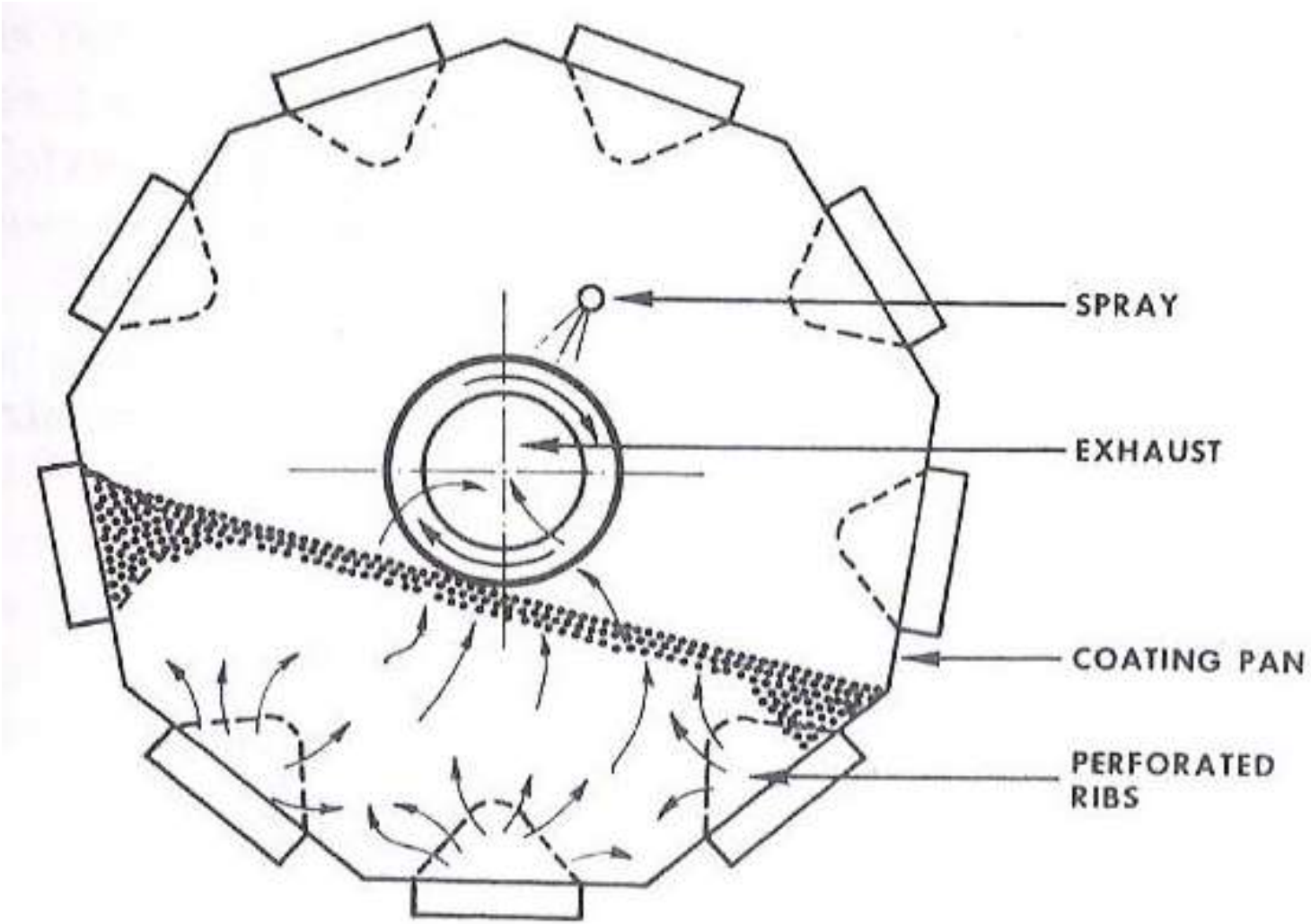
ACCELA COTA & HI COATER SYSTEM-

- Drying air is directed in to the drum,
- Passed through tablet bed,
- Exhausted through perforations in drum.

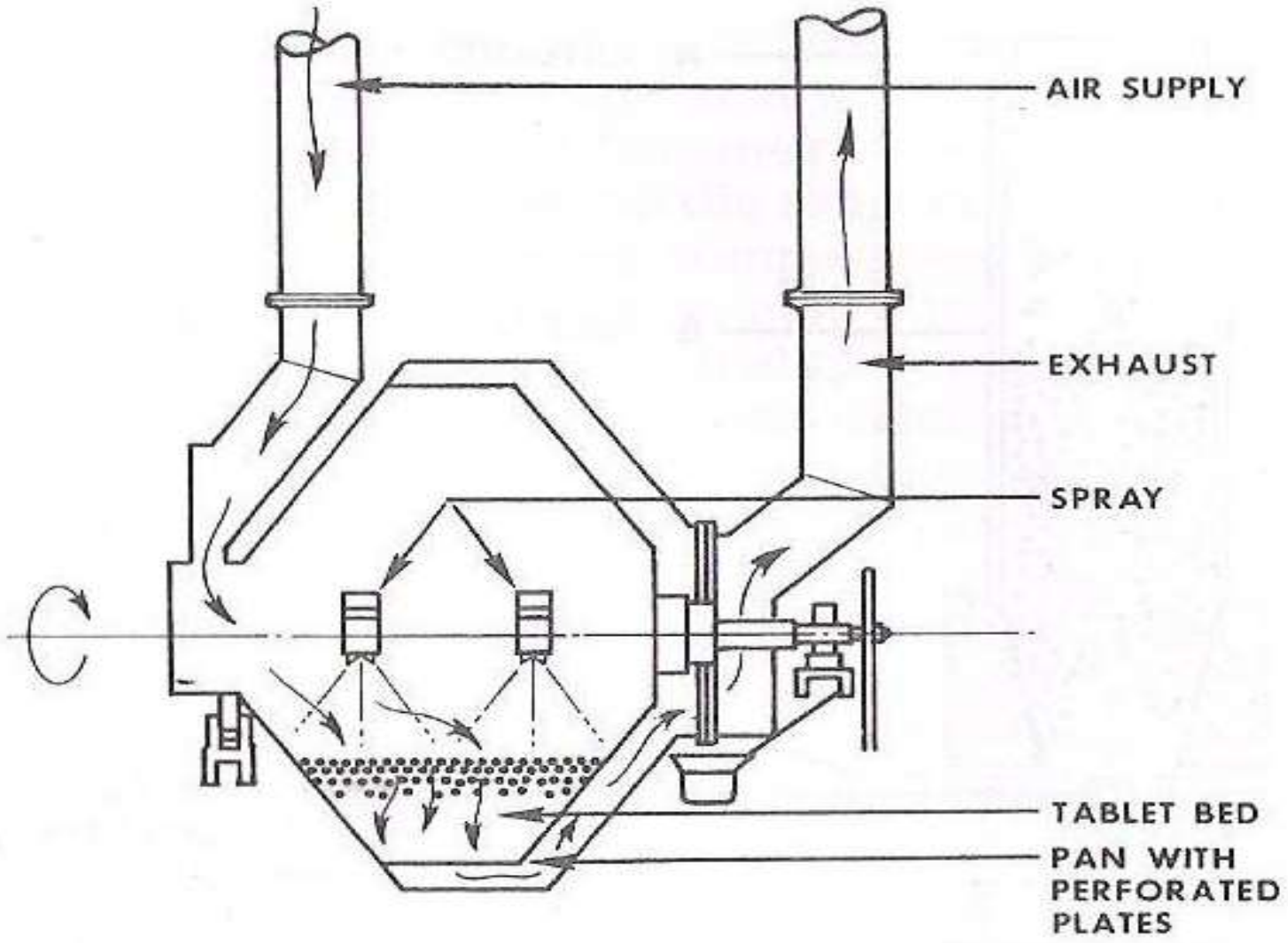
DRIACOATER PAN-

- 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.

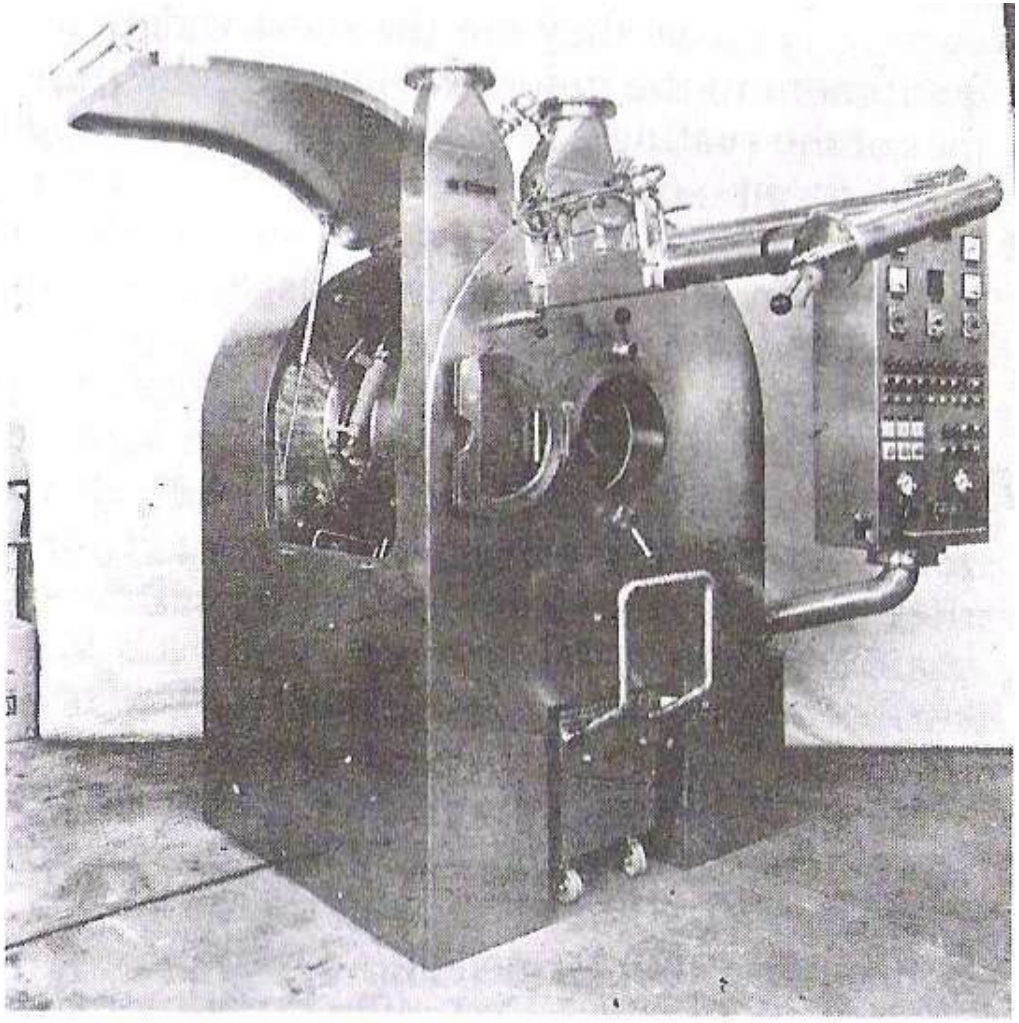
DRIA COATER PAN



HI-COATER SYSTEM



GLATT COATER



GLATT COATER

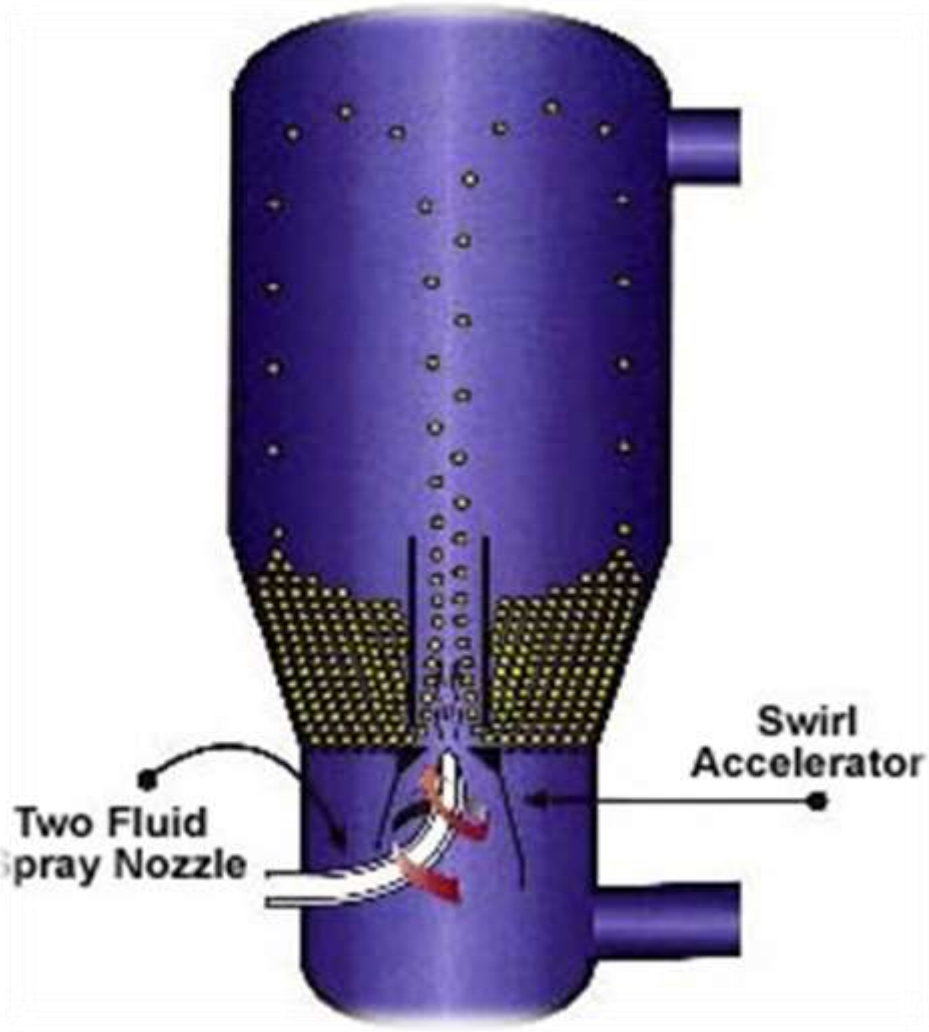
- It is the latest perforated pan coater to be introduced in the industry.
- In this, drying air can be directed from inside the drum through tablet bed
- Exhausted out through an exhaust duct.

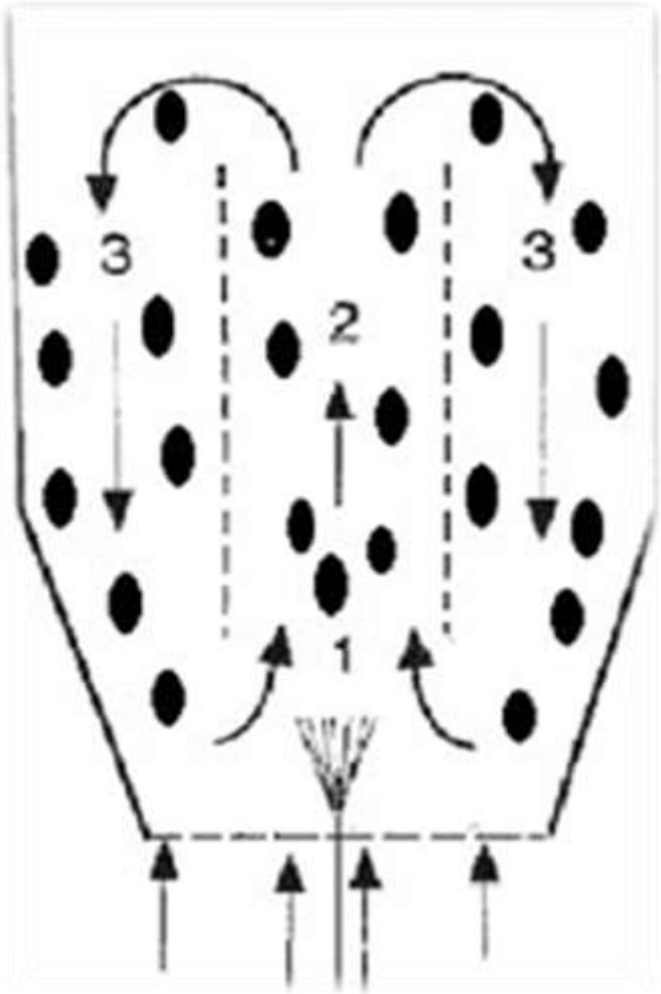
III. FLUIDIZED BED SYSTEM

III. FLUIDIZED BED SYSTEM

- In this system fluidization of the tablet mass is achieved in a columnar chamber by the upward flow of drying air.
- The air flow is controlled, so that more air enters the center of the column, causing the tablets to rise in the center.
- The movement of tablets is upward trough the center of the chamber.

FLUID BED COATING MACHINE MECHANISM





FLUIDIZED BED SYSTEM

- They then fall towards the chamber wall,
- Move downwards to reenter the air stream At the bottom of the chamber.
- Coating solutions are applied from a spray nozzle which is located at the bottom of the chamber.

{Or }

are sprayed onto the top of the Cascading tablet bed by nozzles located in the upper region of the chamber.

SPRAY APPLICATION SYSTEM

- 2 Basic systems used to apply a finely divided (atomized) spray of coating solutions or suspensions on to tablet are-

  * High pressure, airless

  * Low pressure, air atomized

AIR LESS SPRAY SYSTEM-

Liquid is pumped at high pressure{250-3000 pounds per square inch gauge(psig) },

through a small orifice (.009 inch to .020 inch) in the fluid nozzle Which results in a finelydivided spray.

In this ,the degree of atomization & the spray rate are controlled by

Fluid pressure,

orifice size and

Viscosity of the liquid.

LOW PRESSURE 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)

- Low pressure air contacts with the liquid stream at the tip of the atomizer,& a finely divided spray is produced.

- The degree of atomization is controlled by the fluid pressure , Fluid cap orifice
  Viscosity of liquid
  Air pressure
  Air cap design.

TABLET COATING PROCESS

- The coating of tablets classified into three types

I. Sugar coating

II. Film coating

III. Enteric coating

SUGAR COATING

- It involves the application of sugar solution with color for several times to give -

  UNIFORM AND ELEGANT FILM.

ADVANTAGES

- It prevents unpleasant odour ,
- Give sweet taste to tablet by masking bitter taste,
- Highly elegant and glossed tablets are obtained.

DURATION ➔ HOURS-FEW DAYS

- Sugar coating involves following steps -

- ✓ Sealing
- ✓ Sub-coating
- ✓ Syruping(smoothing)
- ✓ Finishing
- ✓ Polishing

- The tablet having deep convex surfaces with thin rounded edges are suitable for sugar coating.

- In sugar coating, the tablet should be resistant to breakage, chipping, and abrasions.

Because sugar coating tends to be long and vigorous.

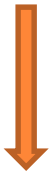
1.SEALING

- It prevents moisture penetration in to the tablet core.
- Seal coating agents - shellac,zein,Oleicacid,PG,PEG4000,alcohol,methylene chloride.

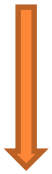
- Zein is alcohol-soluble protein derivative.

- ✓ Shellac is more effective(because of polymerization of shellac),
- ✓ But it lengthens tablet disintegration and dissolution times.

Over wetting of tablet

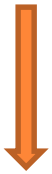


Moisture is absorbed



Leads to

Tablet softening or disintegration



and effects

Physical and chemical stability

(To over come this problem seal coating is done)

2.SUB COATING

- Sub coating is applied :

⇨ To form uniform edges,

⇨ To build up the tablet size.

Sub coating increases the tablet weight from 50 to 100 percent.

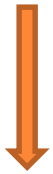
Examples- Gelatin, sugarcane powder, corn syrup, syrup , distilled water, Gum acacia.

- **It involves**

Application of binder solution

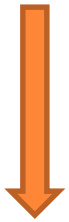
To the

Tablets



followed by

Dusting of sub coating with powders



and drying until

the tablet edges have been covered

&

The desired thickness is achieved.

3.SYRUPING

- It is done to cover the imperfections in the Tablet surface caused during sub coating step.
- It involves-
- Application of syrup coating with grossing syrups followed by the addition of dilute colorants to provide tinted base.
- In subsequent steps, the syrup solution containing dye are applied until

  final size and Color are achieved.

- The final step a clear syrup coat without dye are applied.

❖No colour is added until the tablets are quit smooth,

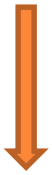
❖Premature application to the rough tablets can produce a Mottled appearance in the final coated tablets.

❖ Syrup coating constituents- colorant , sub coating powder , calcium carbonate ,cane sugar powder, corn starch, syrup , distilled water.

4.POLISHING

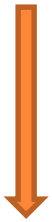
- The desired luster to the tablet is obtained by polishing .

Tablets are polished



in a

Standard coating pans



by application of

carnauba wax(yellow), bees wax(white),paraffin wax

(Or) warm solutions of waxes in naphtha

(or) suitable volatile solvent.

FILM COATING

- It is the process of polymeric solution to bring a uniform film.

Advantages

- Film coating gives a tablet with less Weight and small size.
- The film formed is very thin.
- In film coating engravings are possible on tablet surface which are not possible in sugar coating.

- Better mechanical strength is obtained.
- The cost of the film coated tablets is less.

FILM FORMING AGENTS

The film forming agents tablet coating are classified into:

1.Non - enteric film formers

2.Enteric film formers

NON-ENTERIC FILM FORMERS

- They are incorporated to give uniform film with desired mechanical strength which are as follows:
    1. HPMC(Hydroxy propyl methyl cellulose)
    2. MHEC(Methyl hydroxyl ethyl cellulose)
    3. EC(Ethyl cellulose)
    4. HPC(Hydroxy propyl cellulose)
    5. POVIDONE
    6. SCMC
    7. PG
    8. ACRYLATE POLYMERS

1. HPMC

- It is prepared by reacting alkali treated cellulose with
  methyl chloride with propylene oxide.

- As it forms bridging & rough Tablet surface, it has to
  be mixed with other polymers or plasticizers.

2.MHEC

- It is prepared by reacting alkali treated cellulose with methyl chloride & then with ethylene oxide.

- It has similar properties as that of HPMC,

- But it is soluble in fewer organic solvents, it is not used as frequently as HPMC .

- These polymers used in combinations with other

  polymers to modify film Properties.

- FOR EXAMPLE-

  Combinations of PG waxes with Cellulose acetate phthalate provide film that are soluble in GI fluids.

3.EC

- It is manufactured by the reaction of ethyl chloride with cellulose dissolved in NaOH.
- It is available in different viscosity grades.
- Unplasticized EC forms brittle films & requires film modifiers to obtain acceptable film.

- It is water insoluble & thus Cannot be used alone for tablet coating.

- It is usually combined with water Soluble additives

  E.G.- HPMC to prepare film

  with reduced water soluble Properties

  &This combinations are widely Used

  in sustained release coating.

4.HPC

- It is manufactured by the treatment of

  cellulose with NaOH

  followed by the reaction with propylene oxide

  at

  Elevated temperature and pressure.

- It forms tacky films.

- **Used in combinations with other polymers to improve film characteristics.**

- **It is soluble in water (below 40 ^{o}c & insoluble above 45°*c*) ,**

  GI fluids &
  in many polar
  Organic solvents.

5.POVIDONE

- **It is synthetic polymer consisting of linear 1-vinyl-2-pyrrolidinone groups.**
- **It gives clear, glossy, hard films when dry.**
- **It give tacky films which can be overcome by plasticizer or other polymer.**

6.ACRYLATE POLMERS

- These are marketed under the trade Name of Eudragit.

- Eudragit RL & RS are copolymers of Acrylic and meth acrylic acid esters.

- These films produce pH independent, delayed actions.

- Preparation is similar to that of EC formulations.

ENTERIC FILM FORMERS

- **REASONS FOR ENTERIC FILM FORMERS-**

- To protect acid-labile drugs from gastric fluid e.g. Enzymes & certain Antibiotics.

- To prevent gastric distress or nausea due to irritation from the drug .
  e.g., Sodium salicylate.

- To deliver drugs intended for local Action in the intestines, e.g. Intestinal antiseptics.

- To deliver drugs that are optimally Absorbed in the small intestine to their primary absorption site.

- To provide a delayed-release component for repeat-action tablets.

PROPERTIES OF AN IDEAL ENTERIC COATING MATERIAL

- Resistance to gastric fluids.
- Susceptibility or permeability to intestinal fluids.
- Compatibility with most coating solution components & the drug substrates.
- Stability alone and in coating solution.

  The film should not change on aging.

- Formation of a continuous film, nontoxicity, with low cost.
- Ease of application without Specialized equipment.
- Ability to be readily printed and allow film to be applied to debussed tablets.

ENTERIC FILM FORMERS

- CAP(Cellulose acetate phthalate)
- ACRYLATE POLYMERS
- HPMCP(Hydroxypropyl methyl cellulose phthalate)
- PVAP(Polyvinyl acetate phthalate)

1.CAP

- It is widely used.
- As it is hygroscopic and relatively permeable to moisture and gastric Fluids, film formed **are brittle and** hence formulated with hydrophobic- Film forming materials to achieve better enteric films.
- **Aquateric coating** is a reconstituted colloidal dispersion of latex particles. It is Composed of solid or semisolid polymer spheres of cap ranging in size from 0.05-3 Microns with an a average particle size of 0.2 microns.

2.ACRYLATE POLMERS

- 2 forms of commercially available Enteric acrylic resins are

Eudragit L and Eudragit S.

Eudragit l is available as an organic Solution, solid or aqueous dispersion.

Eudragit s is available only as an organic solution and solid.

Eudragit l & s are soluble in intestinal Fluid at pH 6&7.

3.HPMCP

- It is derived from HPMC by esterification with phthallic anhydride.
- These are stable than cap and dissolve At lower pH compared to cap and acrylate polymers.
- The solubility characteristic may result in Higher bioavailability of some specific drugs.
- It is available in various grades- HP55,HP50 etc.

4 PVAP

- It is manufactured by the esterification of partially hydrolyzed Polyvinyl alcohol with phthallic Anhydride.

- It is similar to HPMCP(HP55) in

stability and

pH dependent solubility.

COATING COMPOSITION

It involves →

1. Solvent

2. Plasticizers

3.Colorants

4.Opaquant-extenders

1.SOLVENT

- It is to dissolve or disperse the polymers and other additives and convey them to the substrate surface.

- **The ideal requirements of the solvent are→**

✓ It should either dissolve or disperse the polymer system.

✓ It should have no environmental impact.

✓ It should easily disperse other coating solution components in to the solvent system.

✓ It should have rapid drying rate(ability to coat 300kg load in 3-5 hours)

- *It should be*

  Colorless, tasteless, odorless, Inexpensive, nontoxic, inert and Noninflammable and rapid drying Rate.

- *Examples-*

  Water, Ethanol, Methanol, Isopropanol, Chloroform, Acetone, Methylene chloride , Methylene ethyl ketone.

2.PLASTICIZERS

- It is used to modify the quality of the film .
- Plasticizing techniques involve internal plasticizers and external plasticizers.
- Internal plasticizers→ involves Chemical modification of the basic polymer that alters the physical properties of the polymers.
- Chemical plasticizers→ Additives of the Coating solution to achieve the desire effect of the film (flexibility ,tensile Strength, adhesive properties)

- Level of plasticizers ranges from 1-50% by weight of film former.

- Examples→

  Castor oil,
  Propylene glycol,
  Glycerin,
  Surfactants

  e.g., →Polysorbate(tweens),sorbitan esters(spans), organicacid esters.

3.COLORANTS

- It is to provide the distinct color and Elegance to the dosage form.

- To achieve the proper distribution of suspended colorants in the coating solutions requires→

  Use of fine powdered colorants

  (<10 microns)

- The concentration of colorants in the coating solution depends on the color shade, desired the type of dye and the concentration of the opaquqnt extenders

- For very light shade→ conc. Lt 0.01%
- For dark shade→ Conc. Mt 2.0% is required.
- The most common colorants in use are certified by FOOD DRUG AND COSMETICS (FD&C) or DRUG AND COSMETIC (D&C) Colorants.
- These are lakes and dyes.
- Lakes are derived from dyes by precipitating with carriers e.g., Alumina or talc.

- The inorganic materials and the natural colorants are-

→ Iron oxides,
→Caramel,
→Carotenoid,
→Chlorophyll, indigo,
→Flavones,
→Turmeric and carminic acid.

- *A variety of products that are Commercially available are-*

- **Opalux-** Opaquant color concentrate for sugar coating.
- **Opaspray** -for film coating.
- **Opadry-** complete film coating concentrate.

OPAQUANT-EXTENDERS

- These are very fine inorganic powders used In the coating solution formulation to provide more pastel colors and increase film coverage.

- Provide white coating or mask the color of the tablet core.

Examples→ Titaniundioxide

Silicates like (Talc, Aluminiumsilicate)

Carbonates like-magnesium carbonate,

Sulphates like calcium sulphate.

FILM DEFECTS

STICKING AND PICKING-Attaching of tablet to another.

REASONS	REMEDY
OVER WETTING	REDUCE LIQUID APPLICATION
RAPID DRYING	CONTROL RATE OF DRYING
TACKINESS OF TABLETS	CHANGE FORMULATIONS

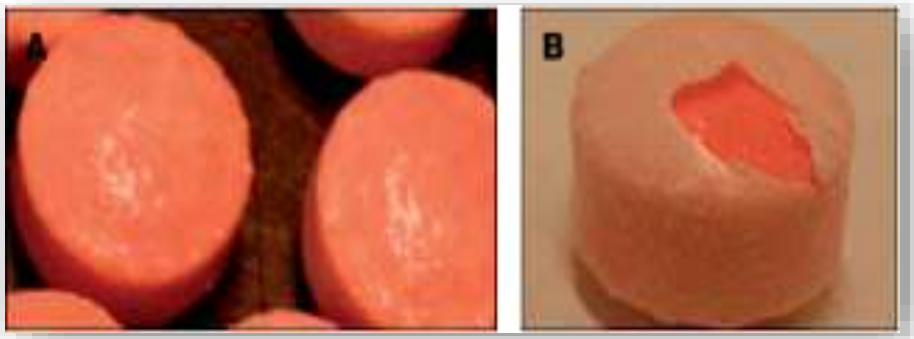
ROUGHNESS- Formation of rough or gritty surface .

REASONS	REMEDY
INCREASE IN PATH LENGTH OF SPRAY NOZZLE TO TABLET BED.	DECREASE IN PATH LENGTH.
RAPID DRYING	CONTROL THE DRYING RATE.

FILM DEFECTS

Picking and sticking

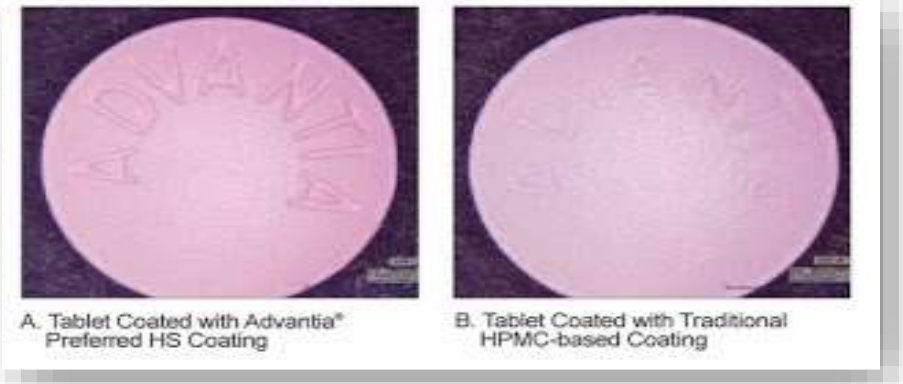
Orange Peel



Capping and Lamination

Roughness

Bridging



Twinning

Erosion

ORANGE PEEL EFFECT- Inadequate of spreading coating solution.

REASONS	REMEDY
RAPID DRYING.	DECREASE IN DRYING RATE.
HIGH VISCOSITY OF COATING SOLUTION.	DECREASE THE VISCOSITY BY ADDING SOLVENT.

BRIDGING – Shrinking or pulling away of film from corners.

REASONS	REMEDY
OVER WETTING.	DECREASE THE APPLICATION RATE.
LESS VISCOUS LIQUIDS.	INCREASE VISCOSITY.
SPREADABILITY PROBLEMS.	CHANGE THE FORMULATION.

BLISTERING-Removal of film due to rapid evaporation of solvent from tablet core.

REASONS	REMEDY
RAPID EVAPORATION OF SOLVENT DUE TO INCREASE IN TEMPERATURE. HIGH VISCOSITY OF COATING SOLUTION.	DECREASE THE TEMPERATURE OF DRYING. DILUTE THE COATING SOLUTION.

- Apart from the all mentioned film coating techniques special techniques are used like

- ✓ COMPRESSION COATING,
- ✓ ELECTROSTATIC COATING,
- ✓ DIP COATING,
- ✓ VACUUM FILM COATING ,
- ✓ DRY COATING ,
- ✓ LAMINATED COATING are used.

CONCLUSION

- Coating is one of the important technique in manufacturing of dosage forms, improve the stability, shelf life and release pattern .
- Coating of dosage forms helps in improving patient compliance.
- Now-a-days, advanced techniques are preferred over the conventional types, because of effective coating, taking less time, and also improve the stability of the product (chances of degradation in coating time).