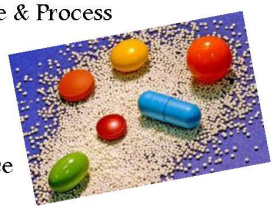
Introduction & History
Objectives
Tablet Properties
Coating Principle & Process
Sugar Coating
Film Coating
Coating Defects
Stability studies
Quality assurance



Coating History

Application of coating to tablet is an extension/ additional step in the manufacturing process, where in tablets were coated with coating material to derive additional benefits.

- Islamic drug literature mentions coated pills by Rhazes (850-923)
- French publications (1600) describe coating as a means of masking the taste of medicines.
- Sugar coating of pills was developed by French in mid 1800s
- Pills were replaced by tablets-process remains same for next 75 years
- 1953 dramatic change noticed –Abbott Laboratories marketed first film coated tablet
- 1950 air suspension coating was patented

Objectives of Coating/why coating?

1) Mask: taste odor & color of drug
2) Stability: Physical & Chemical
3) Control Release: CR, SR, TR, PR & DR
4) Protect drug against GI environment : Enteric coating
5) Incompatibility: Drug & adjuvant
6) Improve elegance , color imprinting & patient acceptance
7) Increases the mechanical strength of the core tablet

Limitations/disadvantages

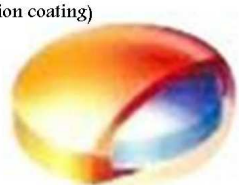
- Coating increases cost of the product
- Technical expertization is required mainly for sugar coating
- Coating solution formulation is based on trial error or optimization
- Use of organic solvents leads to environmental hazards
- Reprocessing of batch is difficult
- Stability kinetics has to be studied for prolonged period.

Types /Classification of coating

- sugar coating
- film coating (aqueous or non aqueous)
- Vaccum film coating
- entricoating
- press coating (compression coating)

Other methods

- Dip coating
- Electrostatic coating
- Laminated coating



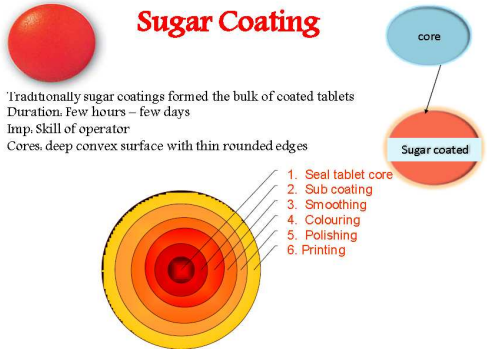
Tablet Properties; Desired

Tablets should possess certain physical characteristics

- **Strength & Hardness.** To tolerate intense attrition of tablet striking other tablet / wall of coating equipment
- **Smooth surface.** rough & brittle surface not suitable for film coating. Surface imperfections is coated not eliminated, in sugar coating due to large solid content can fill many imperfections and cover.
- **Physical shape.** Ideal shape is sphere, however biconvex tablets are suitable as they roll freely & not stick to each other.
- flat-faced/ flat square tablets are difficult to coat
- Dedusted after compression

Sugar Coating

Traditionally sugar coatings formed the bulk of coated tablets
Duration: Few hours – few days
Imp: Skill of operator
Cores: deep convex surface with thin rounded edges



Sugar Coating

- **Seal coating.** To prevent moisture penetration into tablet core. Mainly for pan ladling process (localized over wetting). Otherwise tablet get softened and disintegrate.

  Materials. Shellac (aging effect)
  Zein (protein derivative),
  organic solvents etc…
  cellulose acetate phthalate
  polyvinyl acetate phthalate

1) Tablets are loaded in to pan, dedusted with cold air from blower.
2) Coating solution is added slowly over the tablet bed, hot air is blown over tablet bed. Duration is 5 – 10 minutes
3) Sticking of the tablets are avoided by drying continuously.
4) Smooth uniform coat of tablets without sticking
5) Wt gain is observed

Sugar Coating

- **Subcoating.** Applied to round the edges & build up the tablet size (50-100%).

  Method. Alternate application of sticky binder solution followed by dusting of subcoating powder then drying. Process contd. till tablet edges have been covered & desired thickness is achieved.

  In spray method. suspension containing both binder and subcoating powder is sprayed intermittently on the tablet bed. calcium carbonate or talc as dusting powder & sucrose solution with acacia are as subcoating solution.

  Subcoating solutions: Gelatin, Acacia in syrup & water
  Subcoating powders: Kaolin, Dextrin, sugars etc.

Sugar Coating

- **Smoothing (Syruping).** Cover and fill in the imperfections in the tablet surface caused by subcoating step.

  Require most skill

  Method. syrup coat containing some suspended subcoating powder (grossing syrup) to smoothen the surface

- **Finishing (coloring).** provide elegant color to the coated tablets.

  Method. plain syrup solution containing dye (heavy syrup & regular syrup) are applied until the final size and color are achieved. At the end few clear coats of syrup may be applied to give glossy appearance.

Sugar Coating

- **Polishing.** To obtain desired luster. Carried out in clean std pan or canvas lined polishing pans.

  Method: carefully applying powdered wax (bees/ carnauba) or warm solutions of these waxes in naphtha or other suitable volatile solvent.

- **Printing.** done in automated machines to imprint logo, trademark or any markings.

Sugar Coating

Formulation

- **Seal coat**
  CAP/Zein 10%w/v
  oleic acid/FG/PEG 4000
  Methylene chloride/Alcohol
- **Sub coating (solution)**
  Gelatin & acacia, (0.6%w/v) cane sugar/corn sugar(15%w/v), Distilled water
- **Sub coating powder**
  Kaolin, dextrin, cocoa powder, calcium carbonate, sucrose acacia, starch, talc, calcium sulfate
- **Syrup solutions**
  colorant 5%
  Subcoating powder
  Calcium carbonate/sugar powder/starch
  SyrupIP, Dist water
- **Polishing solutions**
  Carnauba/bees wax/paraffin wax
  Solvent naphtha

TO VISUALIZED THE CONCEPT OF SUGAR COATING

Film Coating

- Involves spraying a solution of polymer + pigments + plasticizers onto a moving tablet bed with simultaneous removal of solvent
- Forms a thin, uniform film on tablet surface
- Except air suspension method, film coating and sugar coating share the same equipment & process parameters
- Film coating; major advantages
  - Appearance
  - Dust elimination
  - Taste masking
  - Isolation/identification
  - Protection
  - Drug release alteration`

Film Coating

Film coating Materials

Ideal film coating material should have the following attributes

1. Solubility in solvent of choice
2. Solubility required for intended use
3. Able to produce elegant product
4. Stability, heat, light, moisture, air etc
5. Essentially no color, taste/ odor.
6. Compatible
7. Inert, non toxic
8. Form thin flexible film
9. No bridging/ filling of debossed tablet surface
10. Ease of printing

Film Coating

METHODS; **Pan pour method & pan spray method**

Pan-Pour Method

- Pouring the specific quantity of coating solution on to the tablet bed followed by mixing and drying.
- Suitable for viscous solutions.
- Slow process and not reproducible, relies heavily on skill of the operator.
- Process needs additional drying step to remove latent solvents.
- Aqueous based film coatings are not suitable by this method due to localized over wetting.

Film Coating

Pan Spray Method.

- Use of spraying device with improved efficiency
- Lends versatility to the process
- Allows for automated control
- Concurrent spraying and drying
- Faster and reproducible technique

Process Variables

- Pan Variables, Pan design and baffling, Speed & Pan load
- Process Air, Air temperature, Air quality & Air flow rate/ volume/ balance
- Spray Variables, Spray rate, degree of atomization, spray pattern & nozzle to bed distance.

Film Coating

Film coating Materials..

Coating materials may be a physical deposition of the materials on tablet surface or they may form a continuous film depending on composition of coating formulation.

Different types of coating materials are

- Synthetic polymers
- Solvents
- Plasticizer
- Colorants
- Opaquant extenders
- Miscellaneous coating solutions

Film Coating

Nonenteric film formers

HPMC, MHEC, EC, HPC, PVP, Na CMC, PEG & Acrylates(Eudragits)

1) HPMC or hydroxypropylmethylcellulose. It is ideal coating polymer with glossy appearance
2) Methylhydroxyethylcellulose; similarity with HPMC but limited solubility with organic solvents.
3) Ethylcellulose; It solubility is good in GIT fluid but it is used along with HPMC
4) PVP; k-30 good film former, glossy and hard film.

Film Coating

Solvents

1. Dissolve/ disperse the polymer & other components
2. Colorless, tasteless, odorless, inexpensive, non-toxic, inert & non flammable
3. Rapid drying rate
4. No environmental impact

Egs: water, ethanol, methanol, isopropanol, chloroform, acetone, methylethylketone, methylene chloride

Film Coating

Plasticizers

Quality and strength of film formers can be modified by use of plasticizers.

Internal: chemically modifying the basic polymer leading to alteration in physicochemical properties.

External: in the form of Additive, it is a non volatile liquid/ another polymer.

Egs: castor oil, PG, Glycerin, PEG 200,400, surfactants etc.

Film Coating

Colorants:

- Either soluble/ suspended in polymer solution.
- Particle size of color should be <10 micron
- Certified FD & C approved dyes and lakes.
- Conc. of 0.01% – 2.0%
- Inorganic (Fe_2O_3) and natural colorants like anthocyanis, caramel, caratenoids, chlorophyll, flavon, turmeric etc.

Opaquants:

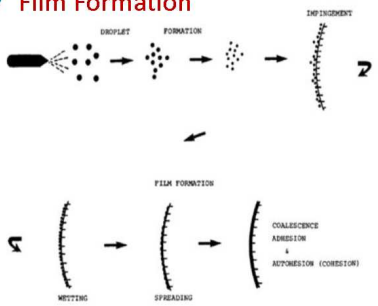
- Fine inorganic powder used in coating to provide briteness to the color. Mask the tablet core color
- Egs: talc, aluminium silicate, carbonates, calcium sulphate etc

Miscellaneous:

- To provide flavor, sweetness, surfactants, antioxidants, antimicrobials,

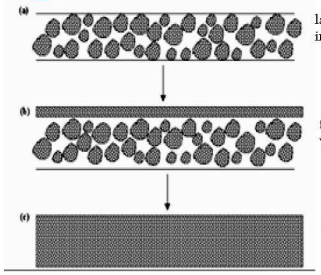
Film Coating

Film Formation



Film Coating

Film Formation



TO VISUALIZED THE CONCEPT OF FILM COATING

Film Coating

Formulations Egs

Non-Aqueous/ Enteric coating composition Sprayed/ poured

S.No	Ingredient	Percentage
1	Cellulose Acetate Phthalate	12 %
2	Propylene Glycol	3 %
3	Sorbitol Mono oleate	1 %
4	Ethanol (200 proof)	45 %
4	Acetone Q.S	100 %

Aqueous, Non enteric Film coating composition

S.No	Ingredient	Percentage
1	HPMC (15 cps)	5%
2	HPC	1 %
3	PEG 400	1 %
4	Pur water Q.S	100 %

Non Aqueous, Non enteric Film coating composition Sprayed/ Poured

S.N	Ingredient	Percentage
1	HPMC (15 cps)	4%
2	PG	1.2 %
3	Ethanol 200 proof	45 %
4	Methylene chloride	100 %

Film Coating

Formulations Egs

Description	Reconstitution level	Average weight gain	Application examples
HPMC based Aqueous system	11% to 15%	2.5 %	Amoxycillin, Azithromycin, Atenolol, Amlodipine, Amitriptyline, Ampicilin Ciprofloxacin, Cephadroxil , Cimitidine, Calcium Tablets, Citrizine , Chloroquine Phosphate, Clarithromycin, Erythromycin, Ferrous Fumarate, Famotidine, Ferrous Sulphate, Ibuprofen, Indapamine, Losartan Potassium, Levamisole, Methyl-Dopa, Metronidazole+Tinidazole, Metronidazole, Methyl Coblamine, Mefenamic Acid, Metoprolol Tartrate, Norfloxacin, Nifidipine, Norfloxacin+Tinidazole, Ofloxacin, Paracetamol, Quinine Sulphate, Roxythromycin, Secnidazole, Sildenafil Citrate, Trimetazidine, Tinidazole, Tinidazole-Doxycycline, Tinidazole + Tetracydine, Verapamil
HPMC based Organic solvent system	5%	2.5%	
HPMC based Aqueous/ Organic Solvent/ Hydro Alcoholic system	Aqueous 11% Organic Solvent 5% Hydro Alcoholic 9%	2.5%	
PVA based Aqueous system	20% to 25%	2.5%	

Major differences between sugar and film coating

Features	Sugar coating	Film coating
Tablets		
Appearance	Rounded with high degree of polish	Retains contour of original core. Usually not as shiny as sugar coat types
Weight increase due to coating materials	30–50%	2–3%
Logo or 'break' lines	Not possible	Possible
Other solid dosage forms	Coating possible but little industrial importance	Coating of multiparticulates very important in modified release forms
Process		
Stages	Multistage process	Usually single stage
Typical batch coating time	Eight hours, but easily longer	1.5–2 hours
Functional coatings	Not usually possible apart from enteric coating	Easily adaptable for controlled release

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 solubilise 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.

Enteric film formers

This equivalent to film coating process but change in the polymer properties ie entricoat polymers are used which are not soluble in gastric fluid but soluble in intestinal fluid

Reasons:

- Protect acid liable drugs
- Prevent gastric distress/ nausea
- Drugs for local action in intestine
- Drugs optimally absorbed in intestine
- Delayed release component of repeat action tablet

Egs: CAP, Acrylate (Eudragit L & S), HPMCP, PVAP etc.

Cellulose acetate pthalate; dissolve at pH 6 & above

Enteric Coating

Description	Reconstitution level	Average weight gain	Application ** examples
Organic Enteric Coating system, Cellulose Acetate Phthalate based	5 %	8 %	Aspirin, Bisacodyl
			Didofenac Sodium
Aqueous coating system & Organic enteric coating system. Hydroxy Propyl Methyl Cellulose Phthalate based system.	Organic: 5% Aqueous: 10%	8 %	Doxylamine Succinate
			Garlic Tablets, Omeprazol, Pentaprazole,
Methacrylic acid copolymer type "C" USP/NF based system	Aqueous 20% Hydro Alcoholic 10% Organic System 10%	9%	Pentoxyfyline, Rabeprazol , Serrosipeptadise

Summary of Polymers used in pharmaceutical formulations as coating materials.

Polymer	Trade name	Application
Shellac	EmCoat 120 N Marcoat 125	▪ Enteric Coatings ▪ Taste/Odor Masking
Cellulose acetate	Aquacoat CPD® Sepifilm™ LP Klucel® Aquacoat® ECD Metolose®	▪ Enteric Coatings ▪ Taste masking ▪ Sustained release coating ▪ Sub coat moisture and barrier sealant pellet coating
Polyvinylacetate phthalate	Sureteric®	▪ Enteric Coatings
Methacrylate	Eudragit®	▪ Enteric Coatings ▪ Sustained Release Coatings ▪ Taste Masking ▪ Moisture protection ▪ Rapidly disintegrating Films

Polymer Quantities

Depending on the desired function of a coating, the following values are figures for the amount of polymer required :

Enteric coatings.

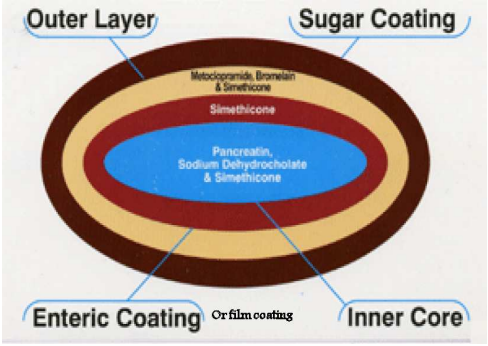
4 – 6 mg for round tablets
5 – 10 mg for oblong-shaped tablets
5 – 20 mg for gelatin or HPMC capsules

Taste-masking coatings.

1 – 2 mg for round tablet
1 – 4 mg for oblong-shaped tablets

Moisture protection.

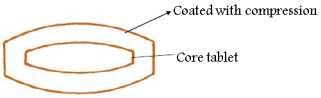
1 – 6 mg for round tablets
2 – 10 mg for oblong-shaped tablets
5 – 10 mg for gelatin or HPMC capsules

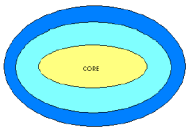


Specialized coating

- Compression coating
- Electrostatic coating
- Dip coating
- Vacuum film coating

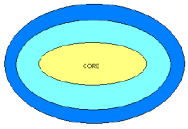
Press coating





Press coating process involves compaction of coating material around a preformed core. The technique differs from sugar and film coating process. It require specialized compression machine . This is two component model ie tablet in tablet. Core tablet is compressed with regular compression and coated with compression with different granules in another compression machine.

Press coating



Advantages

This coating process enables incompatible materials to be formulated together, such that one chemical or more is placed in the core and the other (s) in the coating material.

Disadvantages

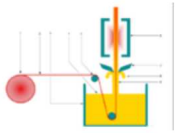
Formulation and processing of the coating layer requires some care and relative complexities of the mechanism used in the compressing equipment.

Electrostatic coating

Electrostatic coating is a manufacturing process that employs charged particles to more efficiently coat a tablet.

Dip coating

Dip coating is a popular way of creating thin films for research purposes. Uniform films can be applied into flat or cylindrical substrates.



Vacuum coating

- It is new technique.
- Coating pan is sealed & vacuum is applied
- Pan is jacked for circulation of hot water for drying of tablets.
- Organic solvent can be recovered
- Highly efficient & economical coating process

COATING EQUIPMENTS

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Coating Equipment

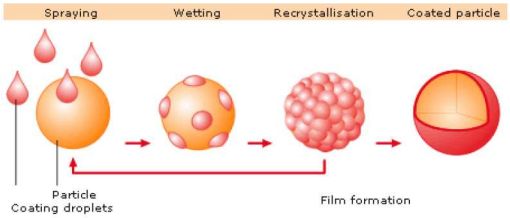
- Standard coating pan ⟶ It is manual
- Perforated coating pan ⟶ It is manual
- Fluidized bed (Air suspension) coater
  - Energy efficient
  - Automated system compatible
  - Reduce operator participation

Coating principle & Process

Tablet coating is the application of a coating composition to a moving bed of tablets with concurrent use of heated air to facilitate evaporation of solvent. Distribution of coating is accomplished by movement of tablets either perpendicular / vertical to the application of coating composition.

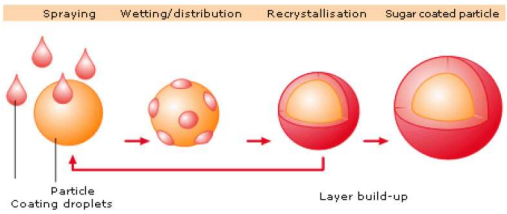
PROCESS:

- Equipment
- Parameters
- Facility & Ancillary equipment
- Automation



A very even application of the coating material is an important feature of the coating process. Coatings must be dense and without mechanical damage and cracks.

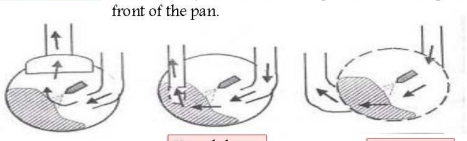
Film coating is an effective process for the application of protective films for manipulating the product characteristics.



Sugar coating is an effective process for the application of thick coating layers, primarily for masking taste. The syrup is sprayed onto the particles. The introduction of the process air evaporates the fluid and dries the sugar coating.

Conventional Pan System

It consists of a circular metal pan mounted somewhat angularly(45) on a stand and is rotated on its horizontal axis by a motor. Heated air is directed into the pan and onto the tablet bed surface, and is exhausted by means of ducts positioned through the front of the pan.



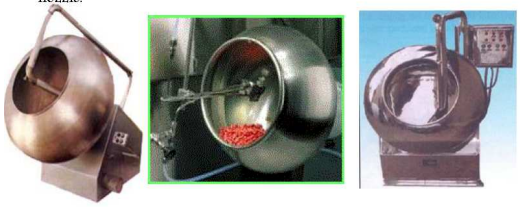
Conventional Coating Pan

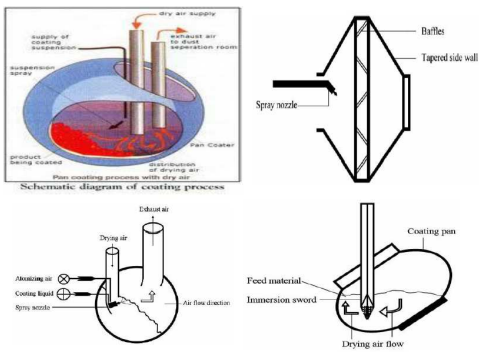
Upgraded Conventional Coating Pan

Side Vented Coating Pan

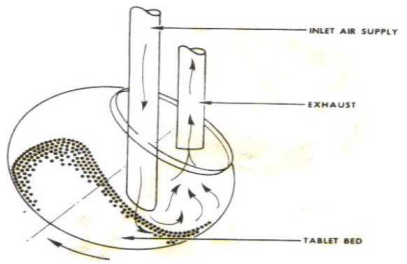
Standard Coating Pan

- Circular metal pan(8– 60 inch diameter) mounted some what angularly on a stand. Rotated on its horizontal axis by motor.
- Heated air is directed into the pan & onto the tablet bed & is exhausted by means of ducts positioned through the front of the pan.
- Coating solutions are applied to tablets by ladling or spraying with nozzle.

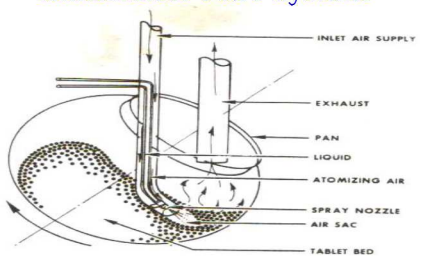




Standard Coating pan



Immersion Tube System



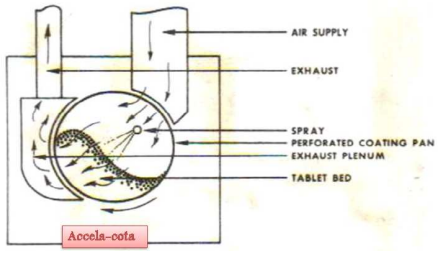
Coating solution simultaneously with heated air from immersed tube
Rapid processing time

Perforated Pan Systems

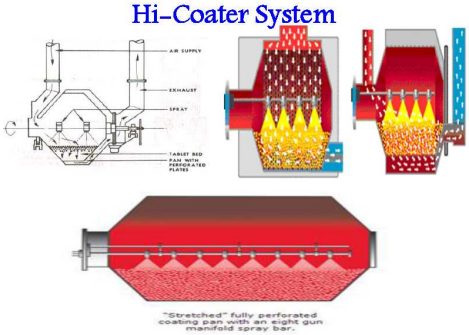
- Consists of perforated or partially perforated drum that is rotated on its horizontal axis in an enclosed system.
- Efficient drying system with high coating capacity
- Can be completely automated for both sugar & film coating

Perforated Pan Systems

In **Accela-cota** and **Hi-coater systems**, drying air is directed into the drum, is then passed through the tablet bed, and is exhausted through perforation in the drum.

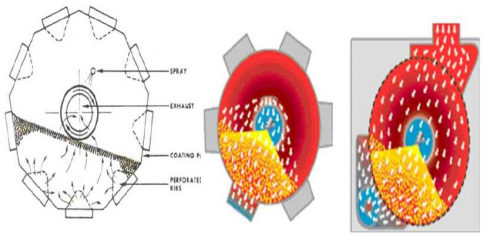


Hi-Coater System



"Stretched" fully perforated coating pan with an eight gun manifold spray bar.

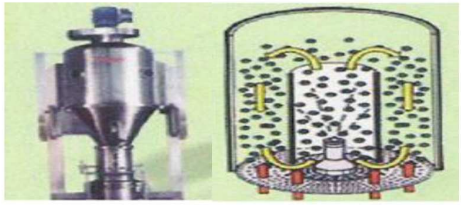
Di-Coater System



Fluidized bed (Air Suspension Coater)

Principle of operation

With fluid bed coating, particles are fluidized and the coating fluid sprayed on and dried. Small droplets and a low viscosity of the spray medium ensure an even product coating.

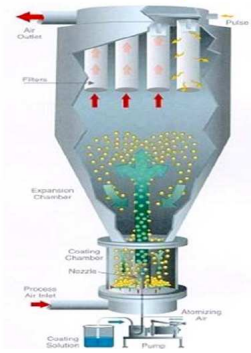


Fluid Bed Coater

Fluidized bed (Air Suspension Coater)

- Highly efficient drying
- Coating solutions are sprayed continuously from a spray nozzle located at bottom, top or tangentially
- Tablets that are friable & prone to chipping may be difficult to coat even under optimum conditions
- Uniform, continuous product coating.
- Aqueous or organic coatings can be applied. Coating and drying take place in one machine.
- In terms of Total Containment, the coating process and the filling and emptying of the machine can be carried out in complete isolation and without product spreading into the environment.
- When using organic solvents, the process machines can also be made inert and used with a solvent recovery system.

Fluidized bed (Air Suspension Coater)

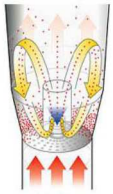


Tablet cores that are friable and prone to chipping and edge abrasion may be difficult to coat even under optimum conditions, owing to relatively rough tablet to tablet impact.

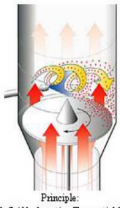
Sprayer positions

Glatt offers Batch Fluid Bed Systems in different batch sizes with:
Top Spray Coating
Bottom Spray Coating (Wurster Coating)
Tangential Spray Coating (Rotor Pellet Coating)

Principle:
Batch fluid bed coating Top Spray



Principle:
Batch fluid bed coating Bottom Spray
(Wurster coating)



Principle:
Batch fluid bed coating Tangential Spray
(Rotor pellet coating)

Spray guns

Close up view of AT Anti-Bearding Manifold Spray Gun.

Spray Application Systems

High pressure airless: liquid is pumped at high pressure(350-3000psig) through small orifice(0.009-0.020 inch) in the fluid nozzle
- -Fluid pressure, orifice size & viscosity of liquid
- -small orifice: suspended solids must be finely milled/ filtered to prevent orifice blockage

Low pressure, air atomized: Liquid is pumped through a somewhat larger orifice(0.020-0.60 inch ID) at relatively low pressure(5-50 psig). Low pressure air(10-100 psig) contacts the liquid stream at the tip of the atomizer; and a finely divided spray is produced.
- - Fluid pressure, fluid cap orifice, viscosity of the liquid, air pressure & air cap design.

Processing parameters

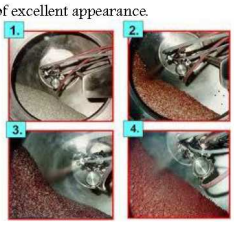
- Air capacity: quantity of water/ solvent that can be removed during the coating process.
- Coating composition: solvent, polymers & adjuvant.
- Tablet surface area: embossing, markings etc
- Equipment efficiency: Ratio of net increase in coated tablet weight to the total non volatile coating weight applied to the tablets & expressed in %. (90-95 sugar coating)
- Inlet and bed temperatures
- Relative humidity
- Atomization air pressure
- Liquid spray rate
- Droplet size
- Drying time

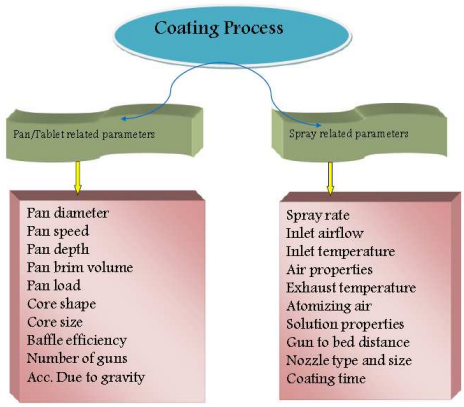
Facilities , ancillary equipment & Automation

- Designed to meet the requirements of cGMP
- Adequate space: coating equipment, solution preparation and in process storage
- Safety requirement for coating areas
- Treatment of exhaust air: recover costly solvents and prevent pollution
- Other equipments : tanks, mixers, pumping devices and filters
- Programmable control systems: software, series of sensors & regulating devices for temp, airflow, spray rate & pan speed.
- In automatic operation perforated pans are preferred over conventional pans

Coating process

- **Sugar coating**
- **Film coating**, Enteric or Non-enteric
  - Type of coating depends on : Objectives of coating, nature of coat, tablet properties etc.
  - Cost, energy, labor, organic solvents, environmental constrains
  - Sugar coating: widely used because of excellent appearance.





Coating defects

S.No	Defect	Remedy
1	**Sticking & Picking**, Tablet stick each other or with pan. After drying, at the point of contact, piece of film adheres to tablet/ pan • Overwetting or excessive film tackiness	• Reduce liquid application rate • Increase drying air temperature • Reformulate coat solution
2	**Roughness**, Droplets dry before reaching tablet surface area, depositing spray dried particles • High pigment / polymer concentration	• Move nozzle closer to tablet bed • Reduce degree of atomization • Decrease pigment/ polymer concentration

Coating defects

S. No	Defect	Remedy
3	**Orange Peel Effect** • Inadequate spreading of coat solution before drying, cause bumpy/ orange feel effect • Too rapid drying • High viscosity	• Slow down drying • Reduce temperature • Thinning coat solution with solvent
4	**Bridging and Filling**, during drying film may shrink, pull away from sharp corners of bisect/ monogram leading to bridging • If above condition is severe ---- ---monogram/ bisect get obscure, due to filling • Applying too much/ too fast coat solution also causes filling	• Reformulate • Change/ increase plasticizer concentration • Decrease application rate • Thorough mixing in pan

Coating defects

S. No	Defect	Remedy
5	**Blistering,** Coated tablets require further drying in oven • Too rapid evaporation of solvent from core • High temperature	• Milder drying conditions 
6	**Hazing/Dull film,** also called bloom • Too high processing temperature • Cellulosic polymers from aqueous media at high temp • Exposing coated tablets to high humidity resulting partial salvation of film	• Reduce processing temperature • Reduce exposure to high humidity 

Coating defects

S. No	Defect	Remedy
7	**Color variation(motling):** due to processing condition/ formulation • Improper mixing • Uneven spray pattern, • Insufficient coating • Migration of soluble dyes, plasticizer/ other additives	• Use of lake dyes • Reformulation with different plasticizer 
8	**Cracking:** Occurs if internal stresses exceed the tensile strength of the film 	• Use of high mol weight polymer/ blend • Plasticizer type and concentration • Pigment type and concentration

Coated Tablet Evaluations

QC test

- ✓ Uniformity in colour, size, & film texture;
  Done by visual inspection
- ✓ Tensile strength; Measure the force required to peel the film from the tablet
- ✓ Resistance to chipping; By rubbing the coated tablets on sheet of white paper if film is soft it will peel off & colour will not impart on paper
- ✓ Hardness by core tablet test
- ✓ Thickness by Varnier calipers
- ✓ Disintegration test; Sugar coated tablets less than 60 minutes.
  Film coated tablets less than 30 minutes
- ✓ Dissolution test; as per core tablets specification

Stability of tablets

- Different temperature and humidity
- 25^0C/RH60%,30^0C/RH65%,40^oC/RH75% ,60^OC/RH80%
- DURATION; 3 months, 6 months, 12 months

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THANK YOU