

Tablet Coating



Tablet Coating

- **Principles**
- **Advantages and disadvantages**
- **Types**
- **Materials, methods and equipment**
- **Coating problems**

The principle of coating process

- Is an additional step in manufacturing of tablets involve the application of coating materials to a moving bed of tablets, with the concurrent use of heated air to facilitate evaporation of the solvent, so we have increase in the weight and cost of the tablets.



Advantages of coated tablets

- ✓ Give protection against environmental and biological conditions.
- ✓ Decrease some side effects (like irritation).
- ✓ Provide modified release and targeting.
- ✓ Masking of the unpleasant taste.
- ✓ Improve appearance and mechanical properties.

Disadvantages (H.w ???)

Types

- Depending on the type of coating material or layer:
 - 1) Sugar coating
 - 2) Film coating
 - 3) Enteric coating
 - 4) Specialized coating

Materials

Involves:

- **Compressed tablets to be coated and the coating materials (Varied with variation of the coating process).**

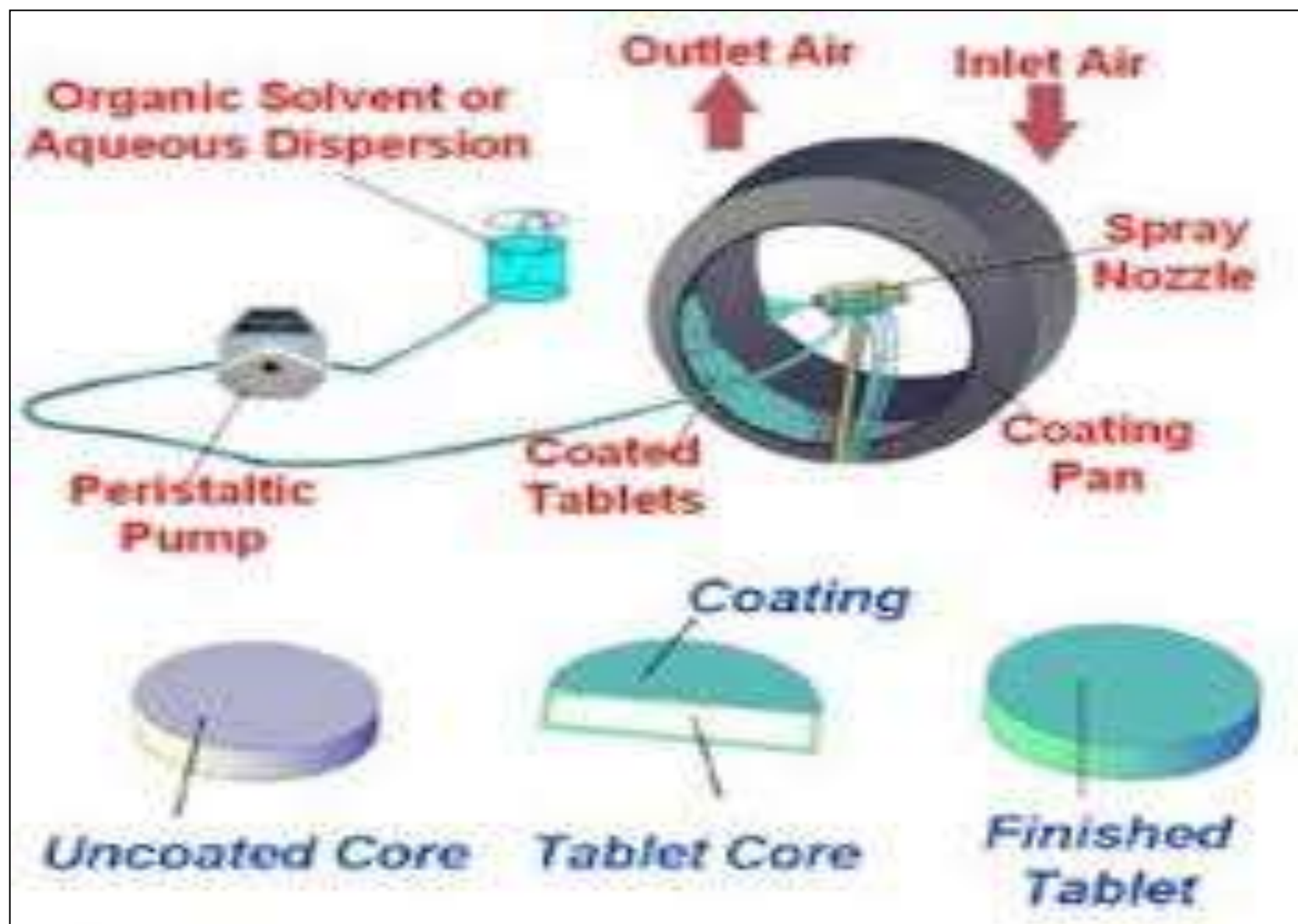
Q/ What are the ideal properties for tablets to be coated?

- 1) Resistance to abrasion and chipping**
- 2) Their surfaces are not affected by coating conditions like heat or moisture.**
- 3) Spherical shape are more preferred than square flat faced tablets.**
- 4) The chemical nature of tablets (hydrophobic or hydrophilic), then S.A.A may be needed or not.**

Coating processes

The general steps for coating process are:

- 1) Agitation of the tablet bed (the whole system or tablet bed).**
- 2) Application of the coating materials. (Spraying or pouring), may be perpendicular or vertical, toward the tablet bed.**
- 3) Evaporation of coating solvents using fresh or hot air.
(Inlet)**
- 4) Removal of vapors using vacuum or perforations. (Outlet)**



Notes:

- In addition to the aqueous dispersions, the applied coating materials may be formulated in form of :
 - 1) Coating solutions (organic or inorganic containing single or multiple solvent system, depending on the physicochemical properties of involved materials).
 - 2) Coating emulsions (o/w) in which oil phase is volatile organic solvent.

- **The type of selected coating process depends on:**

- 1) The nature of API.**
- 2) The type of coating materials to be applied**
- 3) The durability of the tablet core.**
- 4) The economics considerations of the process.**

Sugar Coating Process

Involves several steps (Multistage), the duration of which ranges from a few hours to a few days. The preferred tablet core are with deep convex surfaces and thin rounded edges to facilitate sugar coating. Also, the cores should be relatively resistant to breakage, chipping and abrasion due to the long and vigorous steps of coating.



What are the properties of sugar coating layer?

- **Colored or uncolored one.**
- **Water soluble, quickly dissolved materials.**
- **Durable process**
- **More complicated.**
- **Relatively, less commonly used nowadays.**

What are advantages and disadvantages? H.W

See video>>>

Steps of sugar coating process



Sealing

Provides a moisture barrier (water proofing layer) to increase shelf life, and hardens the tablet surface to decrease attritional effects.

- **Involve application of water-impermeable polymers (sealants) dissolved in organic solvent, its quantity depends on porosity of tablets. (so soaking up for first application may be needed).**
- **Common examples are CAP, polyvinyl acetate phthalate, zein and shellac that has disadvantage of polymerization on aging.**

Sub-coating

- **Represent the actual start of sugar coating process in which there is rapid build up to round off the tablet edges, act as the foundation for the next steps.**
- **There are two types:**
 - 1) Aqueous gum-based solution , then calcium carbonate powder.**
 - 2) Suspension of calcium carbonate in gum/ sucrose solution.**

Grossing/Smoothing (Syrup coating)

- For smoothing and filling the irregularities on the tablet surface due to sub-coating step and increase the size to the desired one.
- As grossing materials, we have simple syrup contains small quantities of pigments, starch, gelatin, acacia or opacifier.

Coloring



- Give the tablets its color (for aesthetic properties) and finished size.
- Colorants may be water soluble or non (lakes) as before.

Polishing

- Give the final elegance (shiny) using a mixture of waxes or hard paraffin wax as polishing agent.



Printing

For identification (Code number, strength or company name are printed)



Film Coating Process

- Application of film (polymer) as coating layer, colored or non, aqueous or organic solution.
- More commonly used because it can give more mechanical properties in less time or steps.
- Give less elegant tablets, but can make protection or modification of release and targeting.
- The main disadvantage is related to use of organic solvent (residual amount).
- Types?



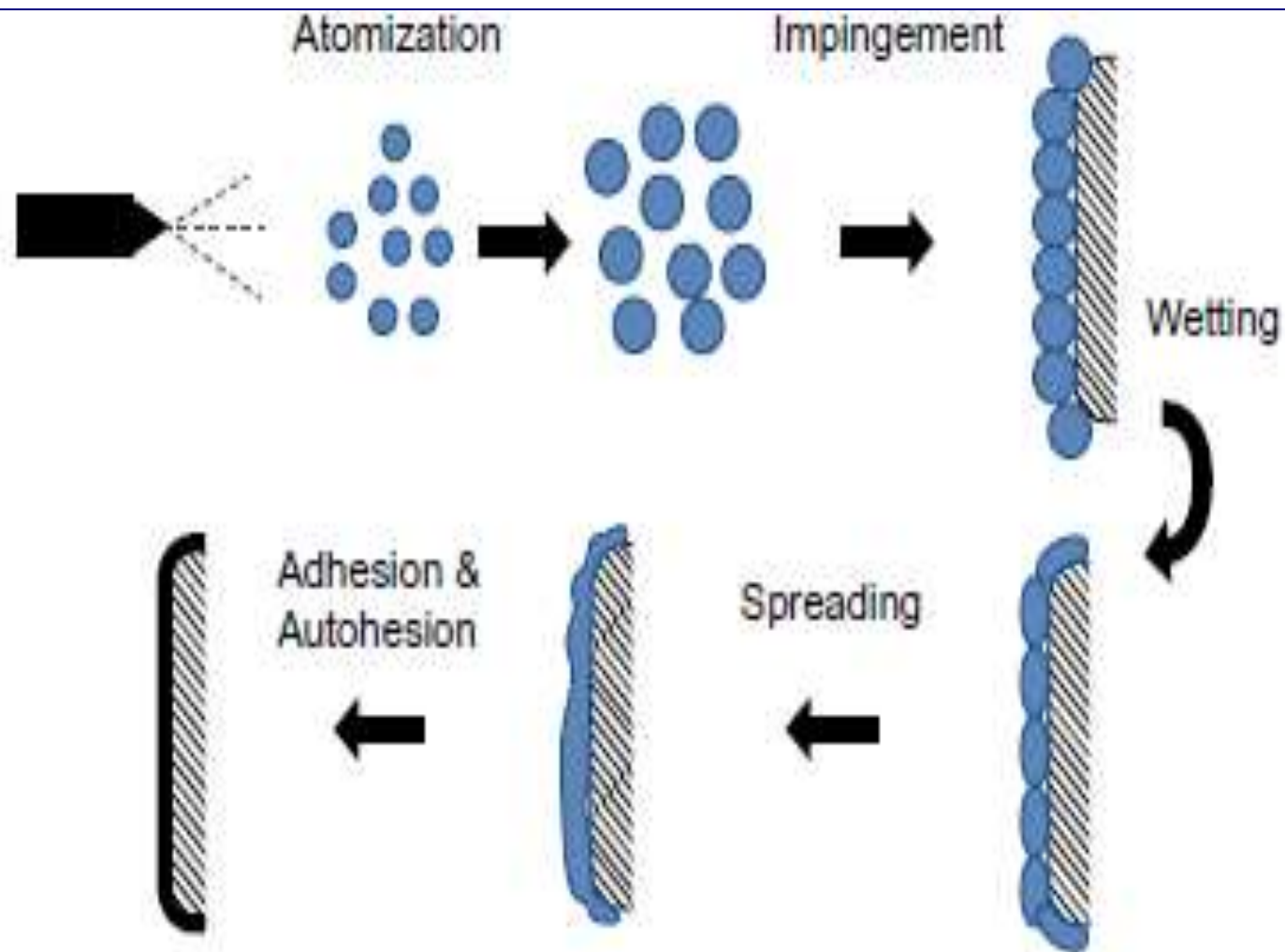


Figure 31-2. Schematic representation of the film-coating process.

- Film coating layer consist of (Film former, solvent, plasticizer, colorant, opaquant-extender and miscellaneous agents).

Film formers

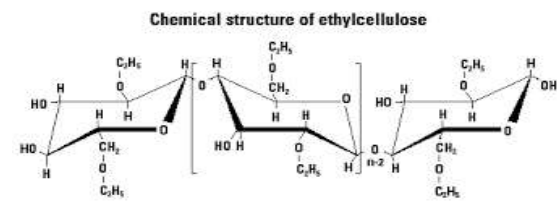
Are polymeric in nature, must be compatible, non-toxic, resistant to cracking with high stability and soluble in the required solvent.

As examples:

Cellulose derivatives (EC, HPMC, MC and HPC),

Acrylate polymers and copolymers (Eudragits) and others

Ethyl Cellulose



- Ethyl ether of cellulose (ethyl oxy group substituent) with different viscosities grades.
- Insoluble in aqueous solutions at all pH values.
- Used in combination with a plasticizer like tri-ethyl citrate for more flexibility properties.



Hydroxy propyl methyl cellulose

- With different viscosities grades.
- Soluble in gastric fluids, organic and aqueous solvent systems.
- Cheap, flexible and highly resistant to heat, light and moisture.
- It has no taste, odor and color.
- Can be used alone or in combination with other polymers or plasticizer for enhancing its film quality.

Acrylate polymer and copolymers

- Found into different physical forms (aqueous dispersion, organic solution, granules and powder)
- Used for targeting of drug release (depend on pH), protection (increase stability) and as retardants.
- Examples: we have Eudragit[®] L-100 (pH>5.5), Eudragit[®] S-100 (pH>7) (Classified as enteric polymers) , Eudragit[®] RL and RS (pH independent release , water insoluble copolymers).

Solvents

- Are used to dissolve or disperse the coating formulation (polymer and other additives).
- Can be used alone or in combinations.
- Are preferred to be cheap, inert, safe with rapid evaporation rates.
- As examples: water, ethanol, methanol, chloroform, acetone and methylene chloride.

Plasticizer

- Used to modify the quality of film (flexibility).
- Its concentration 1-5% by weight of film former.
- Examples: castor oil, PG, glycerin, PEG (200-400), some surfactant.

Colorants

- As before, used in concentrations less than 0.01% for very light shade, and more than 2% for dark color.

Opaquant-extender

- Very fine powder used to provide more pastel colors and increase film enclosing.
- Considered as cheap material, used to decrease amount of colorant used.
- Examples : Titanium dioxide, talc, MgCO_3 and MgO

Miscellaneous

Flavors, sweeteners, surfactant, antioxidant, preservative..

Enteric coating process

■ Used to protect tablet core from disintegration into the acidic media (why?) to,

- 1) Prevent degradation (gastro-resistant tablets)
- 2) Prevent irritation
- 3) Deliver drug to specific organs (targeting).
- 4) Delay the release.



- May be one layer (or application) or two layers (two applications) for more than one aim.
- Examples: CAP, acrylate polymers, shellac, HPMC phthalate.



Specialized coating processes

- **Electrostatic coating : depend on conductive properties between the tablet surface and coating material.**
- **Dip coating: dipping into the coating liquid as in gelcaps (gelatin-coated tablets)**
- **Compression coating: depend on the compression force (compaction of the coating material around the tablet core). It is similar to multilayered tablets**

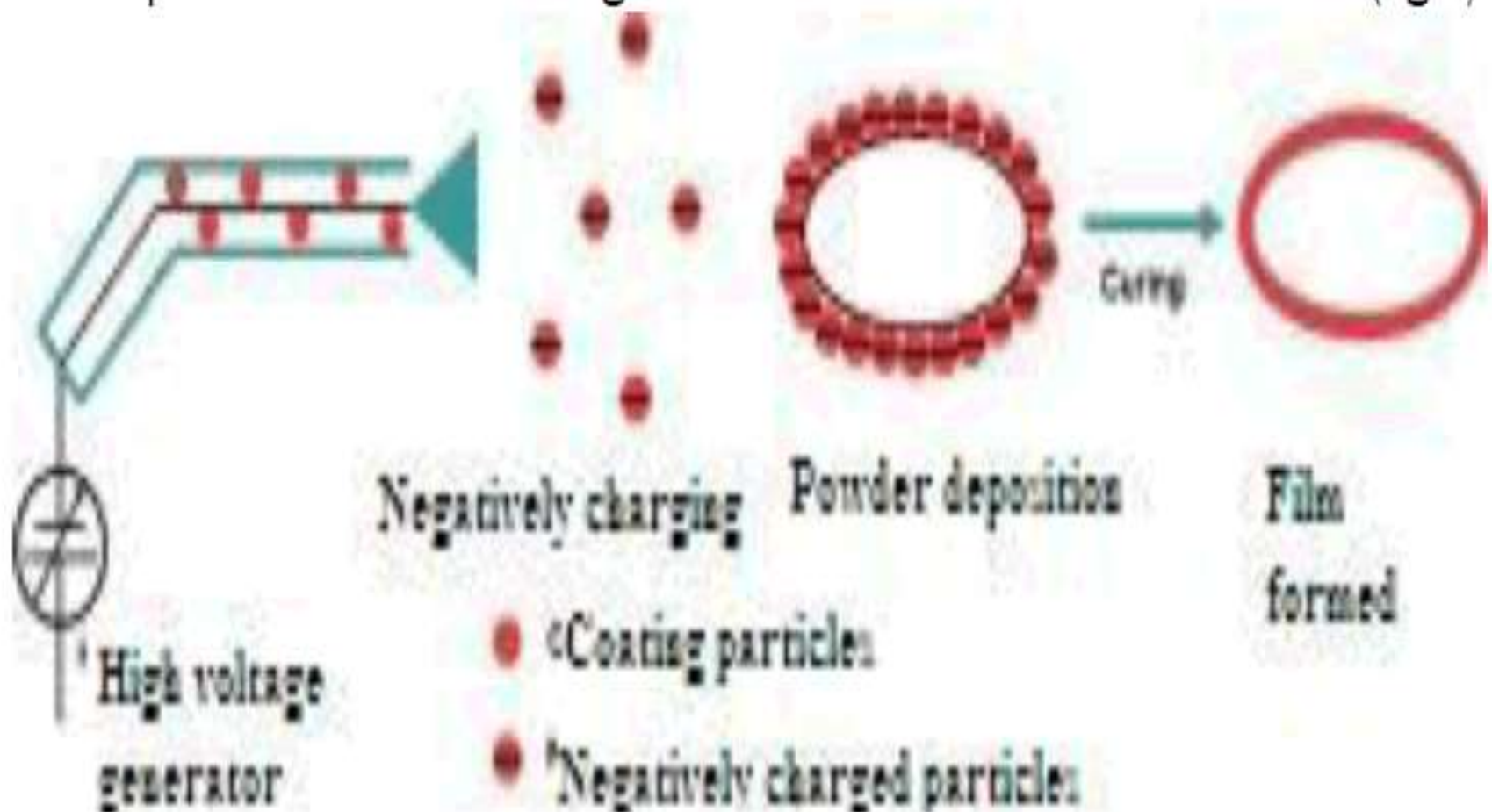


Figure1: Mechanism of electrostatic coating [6].

Questions?

- **What are the differences between sugar and film coating processes?**
- **Give the meaning of :**

The glass transition temperature

Residual solvent amount