

INNOVATIONS IN TABLET COATING TECHNOLOGY: A REVIEW

Neelam D. Kamble^{1*}, Prafulla S. Chaudhari¹, Dr. Rajesh J. Oswal², Sandip S. Kshirsagar²,
Rishikesh V Antre²

¹Department of Pharmaceutics, JSPM's Charak College of Pharmacy & Research,
Wagholi, Pune

²Department of Pharmaceutical Chemistry, JSPM's Charak College of Pharmacy &
Research, Wagholi, Pune

ABSTRACT: Solid dosage forms are coated for a number of reasons, the most important of which is controlling the release profiles and bioavailability of the active ingredient. The amount of coating on the surface of a tablet is critical to the effectiveness of the oral dosage form. Tablets are usually coated in horizontal rotating pans with the coating sprayed onto the free surface of the tablet bed. Tablets must have a coating mass that lies within a prescribed range with very little inter- and intra-tablet coating variability. Using the Discrete Element Method (DEM), tablet coating can be simulated on the computer. Simulation data provide the position, velocity, and orientation of each tablet within the coater, allowing accurate measurements of the time and orientation that each tablet spends exposed to the coating spray.

Keywords: Bioavailability, Rotating pans, Discrete element method (DEM), Spray pattern, spray mass flow rate.

INTRODUCTION**Tablet as dosage form**

A tablet is a pharmaceutical dosage form. It comprises a mixture of active substances and excipients, usually in powder form, pressed or compacted into a solid. Tablets Dosage form is one of a most preferred dosage form all over the world. Almost all drug molecules can be formulated in a tablet and process of manufacturing of tablets is very simple, and is very flexible. One can administered 0.01 mg of a drug dose to 1 gm of a drug dose by oral route of administration, by formulating as a tablet.

Tablet Coating

Coating is a process by which an essentially dry, outer layer of coating material is applied to the surface of a dosage form in order to confer specific benefits that broadly ranges from facilitating product identification to modifying drug release from the dosage form. After making a good tablet, one must often coat it.¹⁻³

Coating may be applied to a wide range of oral solid dosage form, including tablets, capsules, multiparticulates and drug crystals. When coating composition is applied to a batch of tablets in a coating pan, the tablet surfaces become covered with a tacky polymeric film. Before the tablet surface dries, the applied coating changes from a sticky liquid to tacky semisolid, and eventually to a nonsticky dry Surface pans. The entire coating process is conducted in a series of mechanically operated acorn-shaped coating pans of galvanized iron stainless steel or copper. The smaller pans are used for experimental, developmental, and pilot plant operations, the larger pans for industrial production.²⁻³

Basic principles involve in tablet coating

Tablet coating is the application of coating composition to moving bed of tablets with concurrent use of heated air to facilitate evaporation of solvent.

- I. Solution in which influences the release pattern as little as possible and does not markedly change the appearance.
- II. Modified release with specific requirement and release mechanism adapted to body function in the digestive tract.
- III. Color coating which provides insulation.
- IV. To incorporate another drug or formula adjuvant in the coating to avoid chemical incompatibilities or to provide sequential drug release.
- V. To improve the pharmaceutical elegance by use of special colors and contrasting printing.

Primary components involved in tablet coating

- 1) Tablet properties
- 2) Coating process
- 3) Coating equipments
- 4) Parameters of the coating process
- 5) Facility and ancillary equipments
- 6) Automation in coating processes.²⁻³

Coating Process Design & Control

In most coating methods, the coating solutions are sprayed onto the tablets as the tablets are being agitated in a pan, fluid bed, etc. As the solution is being sprayed, a thin film is formed that adheres directly to each tablet. The coating may be formed by a single application or may be built up in layers through the use of multiple spraying cycles.⁷ Rotating coating pans are often used in the pharmaceutical industry. Uncoated tablets are placed in the pan, which is typically tilted at an angle from the horizontal, and the liquid coating solution is introduced into the pan while the tablets are tumbling. The liquid portion of the coating solution is then evaporated by passing air over the surface of the tumbling tablets. In contrast, a fluid bed coater operates by passing air through a bed of tablets at a velocity sufficient to support and separate the tablets as individual units. Once separated, the tablets are sprayed with the coating composition.¹⁻⁷

The coating process is usually a batch driven task consisting of the following phases:

- Batch identification and Recipe selection (film or sugar coating)
- Loading/Dispensing (accurate dosing of all required raw materials)
- Warming
- Spraying (application and rolling are carried out simultaneously)
- Drying
- Cooling
- Unloading

Coating equipment

A modern tablet coating system combines several components:

- a. A coating pan
- b. A spraying system
- c. An air handling unit
- d. A dust collector

Advantages of tablet coating

1. Tablet coatings must be stable and strong enough to survive the handling of the tablet, must not make tablets stick together during the coating process, and must follow the fine contours of embossed characters or logos on tablets.
2. Coatings can also facilitate printing on tablets, if required. Coatings are necessary for tablets that have an unpleasant taste, and a smoother finish makes large tablets easier to swallow.

Disadvantages of tablet coating

- 1) Disadvantages of sugar coating such as relatively high cost, long coating time and high bulk have led to the use of other coating materials.
- 2) However the process of coating is tedious and time-consuming and it requires the expertise of highly skilled technician. r the process is tedious and time-consuming and it requires the expertise of highly skilled technician.

MATERIAL AND METHODS**Techniques**

Generally three methods are used for tablet coating

Sugar coating

Film coating

Enteric coating

Sugar coating process involves five separate operations:

- I. Sealing/Water proofing: provides a moisture barrier and harden the tablet surface.
- II. Subcoating causes a rapid buildup to round off the tablet edges.
- III. Grossing/Smoothing: smoothes out the subcoated surface and increases the tablet size to predetermine dimension.
- IV. Colouring gives the tablet its color and finished size.
- V. Polishing produces the characteristics gloss.

Development of film coating formulations

If the following questions are answered concomitantly then one can go for film coating:

- i) Is it necessary to mask objectionable taste, color and odor?
- ii) Is it necessary to control drug release?
- iii) What tablets size, shape, or color constrains must be placed on the developmental work?

Materials used in film coating

- I. Film formers, which may be enteric or nonenteric
- II. Solvents
- III. Plasticizers
- IV. Colourants
- V. Opaquant-Extenders
- VI. Miscellaneous coating solution components

I. Film formers

(1) Ideal requirements of film coating materials are summarized below:

- i) Solubility in solvent of choice for coating preparation
- ii) Solubility requirement for the intended use e.g. free water-solubility, slow water-solubility or pH -dependent solubility
- iii) Capacity to produce an elegant looking product
- iv) High stability against heat, light, moisture, air and the substrate being coated
- v) No inherent colour, taste or odor
- vi) High compatibility with other coating solution additives
- vii) Nontoxic with no pharmacological activity
- viii) High resistance to cracking
- ix) Film former should not give bridging or filling of the debossed tablet
- x) Compatible to printing procedure

Commonly used film formers are as follow

1. Hydroxy Propyl Methyl Cellulose (HPMC)
2. Methyl Hydroxy Ethyl Cellulose (MHEC)
3. Ethyl Cellulose (EC)
4. Hydroxy Propyl Cellulose (HPC)
5. Povidon
6. Sodium carboxy methyl cellulose
7. Polyethylene glycols (PEG)
8. Acrylate polymers

II. Solvents

Solvents are used to dissolve or disperse the polymers and other additives and convey them to substrate surface.

Ideal requirements are summarized below

- i) Should be either dissolve/disperse polymer system
- ii) Should easily disperse other additives into solvent system
- iii) Small concentration of polymers (2-10%) should not be in an extremely viscous solution system creating processing problems
- iv) Should be colorless, tasteless, odorless, inexpensive, inert, nontoxic and nonflammable.
- v) Rapid drying rate
- vi) No environmental pollution

III. Plasticizers

IV. Colorants

V. Opacant Extenders

VI. Miscellaneous coating solution component

Ideal properties of enteric coating material are summarized as below

- i) Resistance to gastric fluids
- ii) Susceptible/permeable to intestinal fluid
- iii) Compatibility with most coating solution components and the drug substrate
- iv) Formation of continuous film
- v) Nontoxic, cheap and ease of application
- vi) Ability to be readily printed³⁻⁵

Polymers used for enteric coating are as follow

1. Cellulose acetate phthalate (CAP)
2. Acrylate polymers
3. Hydroxy propyl methyl cellulose phthalate
4. Polyvinyl acetate phthalate

New materials used for tablet coating

Zein

Aqua-Zein®, which is an aqueous zein formulation containing no alcohol.

Amylose starch and starch derivatives

Dextrins

Recent trends in tablet coating techniques

Enteric sugar coating, Enteric film coating, Controlled release coating

Specialized coating

1. Compressed coating
2. Electrostatic coating
3. Dip coating
4. Vacuum film coating

Fluid bed rotor Fluid Bed Bottom - spray Wurster

Fluid bed top-spray

Fluid Bed Bottom - spray Wurster

Defects in Tablet Coating

Picking and sticking, Bridging, Capping, Erosion, Twinning, Peeling and frosting, Chipping, Mottled color, Orange peel, Waiting period, Batch size, Solution preparation, Spray gun calibration, Gun geometry Gun nozzles, Bearding.

Evaluation parameters for coated tablets

I. Water vapor permeability

II. Film tensile strength

III. Coated tablet evaluations:

Adhesion test with tensile-strength tester

Diametric crushing strength of coated tablet:

- i. Temperature and humidity may cause film defects.
- ii. Quantification of film surface roughness, hardness, & colour uniformity.
- iii. Mass variance of the coated tablets and variance of the tablet API content.

In process quality control

- I. Weight of tablet - Single pan electric balance
- II. Crushing strength - Controls friability and disintegration time
- III. Tablet thickness - Very thick tablet affect packaging particularly into blisters
- IV. Disintegration time
- V. Friability

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