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The Innovations in Tablet Coating: A Review

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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 solution sprayed onto the free surface of the tablet bed. The advantages of tablet coating are taste masking, odour masking, physical and chemical protection, protects the drug from the gastric environment etc. In these latest technologies coating materials are directly coated on to the surface of solid dosage forms without using any solvent various solvent less coatings are available such as electrostatic dry coating, magnetically assisted impaction coating, compression coating, powder coating and fluid bed coating, supercell coating. Magnetically assisted impaction coating, electrostatic dry coating, coating and Supercell coating technology also are available latest technique of coating. Using the Discrete Element Method (DEM), tablet coating can be simulated on the computer. ICH guidelines also prefer the avoidance of organic solvents in pharmaceutical dosage formulations considering products safety profile. This review discusses the basic concepts of tablet coating, the recent advancements made, the problem faced during the process, their solutions and coating evaluation.***

Keywords: *Tablet coating, Magnetically assisted Impaction coating, Supercell coating, Discrete element method.*

Introduction:

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, multiarticulate 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]

Objectives of coating [4]:

The objectives of tablet coating are as follows:

- To mask the disagreeable odor, color or taste of the tablet.
- To offer a physical and/or chemical protection to the drug.
- To control and sustain the release of the drug from the dosage form.
- To incorporate another drug which create incompatibility problems.
- To protect an acid-labile drug from the gastric environment.
- Increasing the mechanical strength of the dosage form.

Advantages of Tablet Coating[5]:

- Coating is necessary for tablets giving a smoother finish, makes large tablets easier to swallow and also to mask the unpleasant taste.
- Smoother finish makes large tablets easier to swallow.
- Tablet coating does not affect tablet disintegration and drug availability, it is cheap, flexibility, highly resistant to heat, and moisture, no taste and odor, color and additives can be easily incorporated.
- To increase the shelf life of tablet.
- To enhance the aesthetic appeal and brand image.

- To provide enteric release properties for release in the intestinal tract.

Disadvantage of Tablet Coating[5]:

- Tablet coating increase the cost of formulation.
- Tablet coating may interfere in pharmacodynamic properties of drug formulation.
- Something coating may result in various film defects like, mottling, capping, chipping, bridging.
- The process remained complicated.

Coating Process[6,7]:

The coating may be shaped with the aid of an unmatched application or can be constructed up in layers through the use of more than one spraying cycles. Rotating coating pans are regularly used within the pharmaceutical industry. Uncoated tablets are located inside the pan and the liquid coating answer is brought into the pan even as the tablets are tumbling.

Types of Coating:

1. **Sugar coating:** Compressed tablets may be coated with colored or uncolored sugar layer. The coating is water soluble and quickly dissolves after swallowing.

   Sugar coating process involves five separate operations:

   A) ***Sealing/Water proofing:*** The seal coat provides a moisture barrier and hardness the surface of the tablet in order to minimize attritional effects. Common materials used as a sealant include Shellac, Zinc, Cellulose acetate phthalate (CAP), Polyvinyl acetate phthalate, Hydroxyl propyl cellulose, Hydroxyl propyl methylcellulose etc.

   B) ***Sub coating:*** is the actual start of the sugar-coating process and provides the rapid buildup necessary to round up the tablet edge. It also acts as the foundation for the smoothing and color coats.

   C) ***Groosing/Smoothing:*** The grossing/ smoothing process is specifically for smoothing and filing the irregularity on the surface generated during sub coating. It also increases the tablet size to a predetermined dimension.

   D) ***Color Coating:*** This stage is often critical in the successful completion of a sugar-coating process and involves the multiple application of syrup solution (60-70% sugar solid) containing the tablet coating.

   E) ***Polishing:*** Sugar-coated tablets needs to be polished to achieve a final elegance. Polishing is achieved by applying the mixture of waxes like beeswax, carnauba wax, candelilla wax or hard paraffin wax to tablets in polishing pan.

2. **Film Coating:** Film coating is more favored over sugar coating. Materials used in film coating

   - Film formers (which may be enteric or non-enteric)
   - Solvents
   - Plasticizers
   - Colorants

Recent Technologies in Tablet Coating:

Electrostatic Coating:

It is an effective way of applying a coat on conductive substances. A strong electrostatic charge is applied to the substrate. The coating material consisting of conductive ionic species of opposite charge is sprayed on the charged substrate. A complete and uniform coating of corners on the substrate is achieved (fig.1).

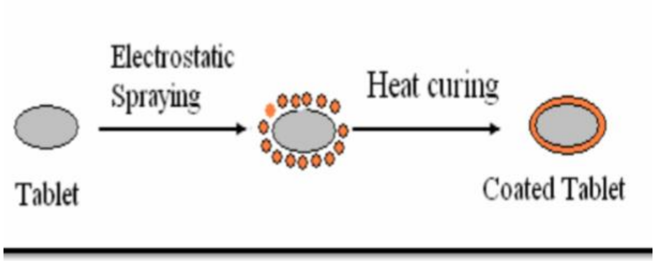

Fig 1: Mechanism of electrostatic coating.

There are two kinds of spraying units, based on the charging mechanism:

a) Corona charging
b) Tribo charging.

a) ***Corona Charging:*** This is done by the electrical breakdown and then ionization of air by imposing high voltage on a sharp pointed needle like electrode (i.e. charging pin) at the outlet of the gun. The powder particles pick up the negative ions on their way from the gun to the substrate. The movement of particles between the charging gun and the substrate is mainly governed by the combination of electrical and mechanical forces. The mechanical forces produced by the air blows the powder towards the substrate from the spray gun. For the corona charging, the electrical forces are derived from the electrical field between the charging tip of the spray gun and the earthen substance, and from the repulsive forces between the charged particles. The electrical field can be adjusted to alter the powder's flow, control pattern size, shape, and powder density as it is released from the gun. [8-9]

b) ***Tribo charging:*** Unlike corona charging guns, the tribo charging makes the use of the principle of friction charging associated with the dielectric properties of solid materials and therefore no free ions and electrical field will be present between the spray gun the grounded substance. For tribo charging guns, the electrical forces are only regarded to the repulsive forces between the charged particles. After spraying when charged particles move into the space adjacent to the substrate, the attraction forces between the charged particles and the grounded substrate makes the particle to deposit on the substrate. Charged particles are uniformly sprayed onto the earthen substrate in virtue of mechanical forces and electrostatic attraction. Particles accumulate on the substrate before the repulsion force of the deposited particles against the coming particles increase and exceed the electrostatic attraction. Finally once the said repulsion becomes equivalent to the said attraction, particles cannot adhere to the substrate any more, and the coating thickness does not increase any more. [10-11]

Magnetically Assisted Impaction Coating (MAIC):

Many dry coating methods have been developed such as compression coating, plasticizer dry coating, heat dry coating and electrostatic dry coating. These methods generally allow for the application of high hearing stresses or high impaction forces or exposure to higher temperature to achieve coating. The strong mechanical forces and the accompanying heat generated can cause layering and even embedding of the guest particles onto the surface of the host particles. Many food and pharmaceutical ingredients, being organic and relatively soft, are very sensitive to heat and can quite easily be deformed by severe mechanical forces. Hence, soft coating methods that can attach the guest (coating material) particles onto the host (material to be coated) particles with a minimum degradation of particle size, shape and composition caused by the buildup of heat are the better candidates for such applications.[12-13] The magnetically assisted impaction coating (MAIC) devices can coat soft organic host and guest particles without causing major changes in the material shape and size (fig.2).

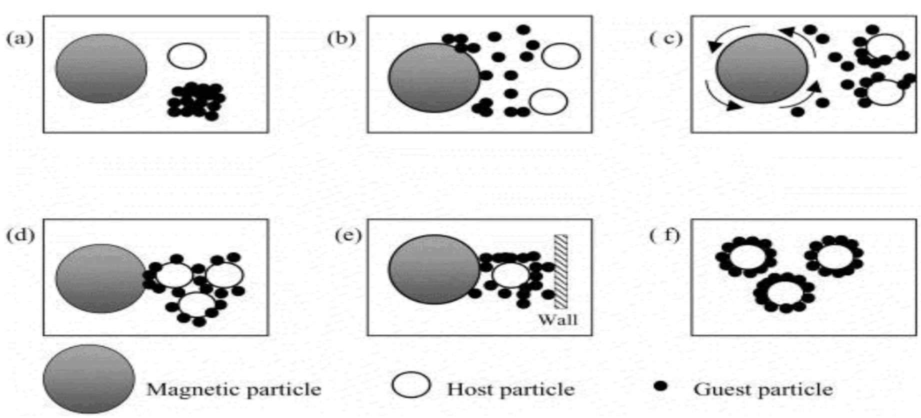

Fig 2: Mechanism of coating in the MAIC process: **(a)** excitation of magnetic particle, **(b)** de-agglomeration of guest particles, **(c)** shearing and spreading of guest particles on the surface of the host particles, **(d)** magnetic–host–host particle interaction, **(e)** Magnetic–host–wall interaction and **(f)** coated products.[14]

Although there is some heat generated on a microscale due to the collisions of particles during MAIC, it is negligible. This is an added advantage when dealing with temperature sensitive powders such as pharmaceuticals.

Discrete Element Method (DEM):

In the pharmaceutical industry, drum coating is routinely used for the production of film tablets. In order to produce a high-quality product, it is important to understand this seemingly simple process in great detail. In our study we present the implementation of three different methods to include spray coating in DEM simulations (Fig 3): (1) an enhanced “spray zone approach” working during run-time, (2) the “discrete drop method”, a novel approach for tablet coating also applied at run-time, and (3) the “ray-tracing method”, which is applied after the DEM simulation using the saved data. Each method is described in detail. For evaluation purposes, the different models were applied to simulate the same coating process, and the comparability, advantages and limitations are discussed. In general, all three methods can give comparable results. However, the spray zone approach depended heavily on its model parameters; the discrete drop method was more reliable and versatile. While the time resolution is higher for the first two methods listed above, the third is faster and more flexible[15].

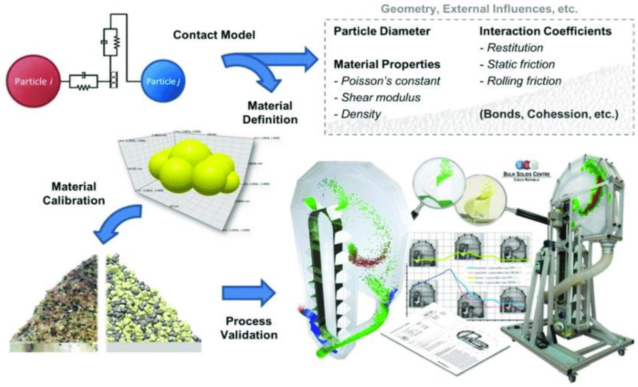

Fig 3: Representation of DEM Principles [17]

Super Cell Coating:

The standard practice of tablet coating often delivers a non-homogenous product. Because the tablets are loaded in large rotating pans and vented for hot air drying, edges of tablets can get grounded off and intagliation can get filled in by coating material leading to uneven coating on edges/corners and tablet faces. Supercell Coating Technology may also be used for coating of flat or highly oblong tablets or friable tablets. In this process, drying is very fast, making it possible to coat extremely hygroscopic tablets. The deposition accuracy is sufficiently high to layer API onto tablets, and uniform layers of taste masking or modified release coatings can be applied consecutively within a single continuous batch.

Unique features of super cell coating technology are:

(1) Continuous coating

(2) Short processing time

(3) Flexible modular design

(4) No scale-up to parameters

(5) Batch size for R&D (Minimum size ~30 grams)

(6) Enhancing technology

(7) Multi-layer coating

Vacuum Film Coating:

It is new coating technique that employs specially designed baffled pan. The pan is hot and water jacketed and it can be sealed to achieve a vacuum system. The tablets are placed in pan and the air in the pan is displaced by nitrogen before the desired vacuum level is obtained. The coating solution is applied by airless spray system. The vapors of the evaporated solvents are removed by vacuum system. Organic solvents can be effectively used with this coating techniques and high environment safety is also there.

Compression Coating:

Compression coating is not widely used, but it has advantages in some cases in which the tablet core cannot tolerate organic solvents or water and yet needs to be coated for taste masking, or to provide delayed or enteric properties to the product. In addition incompatible ingredients can be conveniently separated by process. This type of coating requires a specialized tablet machine.

Dip Coating:

Coating is applied by dipping them into coating liquid the wet tablets are dried in conventional coating pans. Alternate dipping and drying steps may be repeated several times to achieve the coating of desired one. The process lacks the speed, versatility, and the reliability of spray coating techniques.

Defects and Solutions of coated tablets:

S.no	Defect [18]	Reasons [19-20]
1	Picking and sticking	This is when the coating removes a piece of the tablet from the core. It is caused by over-wetting the tablets, by under-drying, or by poor tablet quality.
2	Bridging	This occurs when the coating fills in the lettering or logo on the tablet and is typically caused by excess application of the solution, poor design of the tablet embossing, high coating viscosity, high percentage of solids in the solution, or improper atomization pressure.
3	Erosion	This can be the result of soft tablets, an over-wetted tablet surface, inadequate drying, or lack of tablet surface strength
4	Twinning	This is the term for two tablets which stick together, and it's a common issue with capsule shaped tablets. Suppose you don't want to change the tablet shape, you can solve this problem by changing the pan speed and spray rate. Try lowering the spray rate or increasing the pan speed. In some cases, it is necessary to alter the design of the tooling by very slightly changing the radius. The change is almost impossible to see, but it solves the twinning problem.

5	Peeling and frosting	This is a defect where the coating peels away from the tablet surface in a sheet. Peeling indicates that the coating solution did not lock into the tablet surface. This could be due to a defect in the coating solution, over-wetting, or high moisture content in the tablet core.
6	Blistering	Too rapid evaporation of solvent from the coated tablets and the effect of high temperature on the strength and elasticity of the film may cause blistering. Milder conditions are required in this case.
7	Mottled colour	This can happen when the coating solution is improperly prepared, the actual spray rate differs from the target rate, the tablet cores are cold, or the drying rate is out of spec.
8	Orange peel	This refers to a coating texture that resembles the surface of an orange. It is usually the result of high atomization pressure in combination with spray rates that are too high

Coated Tablet Evaluation:

Determination of the quality of a tablet coat involves studying of the film and the film-tablet interactions. The following test methods can be employed.

Adhesion test with tensile strength testers are used to measure the force needed to peel the film from the tablet surface.

Diametric crushing strength of the coated tablets is determined using a tablet hardness tester. The rate of coated tablet disintegration and dissolution should also be studied. Stability studies can be conducted on coated tablets to verify whether temperature and humidity changes would result in film defects.

Exposure to elevated humidity and measurement of tablet weight gain provide relative information on the protection provided by the film [16]

Conclusion:

From the last three decades, coating of pharmaceutical formulations including tablet coating have been subject of remarkable developmental efforts aiming to ensure and enhance the final product quality. Improvements regarding energy consumption, film distribution, drying efficiency and continuous processing have contributed to significantly develop this technology with improved safety profiles. In future there is enormous possibility of developments in the area of tablet coating to achieve specific benefits.

References:

1. Lachman L., Lieberman, H. A., Joseph L. K. The Theory and Practice of Industrial Pharmacy; Varghese Publishing House; Mumbai; Third Edition; Pp .297-321.
2. Lachman L., Liberman H., and Kanig J. The Theory and Practice of Industrial Pharmacy; Third Edition: 293-345, 346-373.
3. Aulton M. Pharmaceutics: The Science of Dosage Form Design; International Student Edition: 304-321, 347-668.
4. Remington's The Science and Practice of Pharmacy. Volume-I. 21st ed. Indian Edition, Lippincot Williams and Wilkins. 2005: 929-938.
5. Kamble N. et al. Innovations in tablet coating technology: A review. International Journal of Applied Biology and Pharmaceutical Technology. 2011; 214-218.
6. Remington's The Science and Practice of Pharmacy. Volume-I. 21st ed. Indian Edition, Lippincot Williams and Wilkins. 2005; 929-938.
7. Cole G, Hogan J, Aulton M. Pharmaceutical Coating Technology. Taylor and Francis, London, 1995; 1-5.
8. Qiao M. et al A Novel Electrostatic Dry Powder Coating Process for Pharmaceutical Dosage Forms: Immediate Release Coatings for Tablets. European J Pharm Biopharm. 2010: 304-310.
9. Pawar A. et al Advances in Pharmaceutical Coatings. International Journal of ChemTech Research. 2010: 733-737.
10. Mazumder M, Sims R, Biris A. Twenty-first century research needs in electrostatic processes applied to research needs in electrostatic processes applied to industry and medicine. Chem Eng Sci. 2006; 61: 2192-2211.
11. Hogan, John E, Page, Trevor R, Linda S, John N. Powder coating composition for electrostatic coating of pharmaceutical substrates. US Patent 6, 406, 738. 2002 June 18.
12. M.Ramlakhan, Chang Yu Wu, Satoru Watano, Rajesh N. Dave, Robert Pfeffer, Dry particle coating using magnetically assisted impaction coating: modification of surface properties and optimization of system and operating parameters. Powder Technol. 2000; 112(1-2): 137-148.
13. Mazumder M, Sims R, Biris A. Twenty-first century research needs in electrostatic processes applied to research needs in electrostatic processes applied to industry and medicine. Chem Eng Sci. 2006; 61: 2192-2211.

14. Remington J. Remington: The Science and Practice of Pharmacy; Nineteenth Edition: Volume II 1615-1641.
15. American Pharmaceutical Reviews; 2001; 4(3): 28-35.
16. Vyas S., Khar R. Controlled Drug Delivery Concepts and Advances; First Edition: 219-256.
17. https://scholar.google.com/scholar?rlz=1C1_____enIN838IN838&um=1&ie=UTF-8&lr&cites=7256284450029155024
18. Porter SC, Felton LA. Techniques to assess film coatings and evaluate film-coated products. Drug Development and Industrial Pharmacy 2010; 36: 128–42.
19. Pawar A et al. Advances in Pharmaceutical Coatings. International Journal of Chem. Tech Research 2010; 5: 733-737.
20. Srivastava S, Mishra G. Fluid Bed Technology: Overview and Parameters for Process Selection. International Journal of Pharmaceutical Sciences and Drug Research 2010; 2(4): 236-246