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Techniques of Tablet Coating: Concepts and Advancements: A Comprehensive Review.

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Review Article

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ABSTRACT

Tablet coating is one of the oldest pharmaceutical processes still is existence. 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 over uncoated variety. It involves application of a sugar or polymeric coat on the tablet. The advantages of tablet coating are taste masking, odor masking, physical and chemical protection, protects the drug in the stomach, and to control its release profile. Coating may be applied to a wide range of oral solid dosage form, such as particles, powders, granules, crystals, pellets and tablets. When coating composition is applied to a batch of tablets in a coating pan, the tablet surfaces become covered with a tacky polymeric film. There are several techniques for tablet coating such as sugar coating, film coating and enteric coating. The disadvantages of the older techniques of coating have been overcome with the recent advancement in coating technologies. In these technologies coating materials are directly applied on the surface of the tablet without the use of any solvent. 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.

INTRODUCTION

Tablet coating can be described as a process of applying an edible paint on the surface of a pharmaceutical dosage form to achieve specific benefits. This is an additional process in tableting which causes an increase in the cost of tablet production. Coating can be applied to several kinds of solid dosage forms like tablets, pellets, pills, drug crystals, etc. When a coating solution is applied to a batch of tablets in a coating pan, the surfaces of the tablets get covered with a tacky polymeric film. The tablets are then allowed to dry and the film eventually forms a non-sticky dry surface. The coating technique involves parameters such as the spray pattern, drop size, and nozzle spacing (in addition to multiple other non-spray related parameters) which must all be precisely controlled in order to ensure uniform distribution of the coating material [1, 2].

Objectives of coating [3]

- 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.

Coating process

It is most desirable that the coating should be uniform and should not crack under stress. Hence, various techniques were designed for the application of the coating on the tablet surface. Generally, the coating solutions are sprayed onto the uncoated tablets as the tablets are being agitated in a pan, fluid bed, etc. As the solution is being applied, a thin film is formed which sticks to each tablet. The liquid portion of the coating solution is then evaporated by passing air over the surface of the tumbling pans. The coating may be formed either by a single application or may be developed in layers through the use of multiple spraying cycles. Rotating coating pans are often used in the pharmaceutical industry.

Sugar coating

Tablet coating developed originally from the use of sugar to mask the taste and provide an attractive appearance to at the core. The process of tablet coating consists of several steps, which are described below:

Sealing

A seal coat is applied over the tablet to prevent moisture penetration into the tablet core. Shellac was previously used as a sealant. But due to polymerization problems, it was replaced by zein (a corn protein derivative).

Sub coating

This step is done to round the edges and increase the tablet weight.

Syrup Coating

The imperfections in tablet surface are covered up and the predetermined size is achieved. This step requires the maximum skill.

Coloring

Gives the tablet its final color.

Polishing

Powdered wax (beeswax or carnauba) is applied to provide a desired luster.

Film coating

As the sugar coating process is very time consuming and is dependent on the skills of the coating operator, this technique has been replaced by film coating technology. The process involves spraying of a solution of polymer, pigments and plasticizer onto a rotating tablet bed to form a thin, uniform film on the tablet surface. The choice of polymer mainly depends on the desired site of drug release (stomach/ intestine), or on the desired release rate. Some of the non-enteric coating polymers are Hydroxyproply methyl cellulose (HPMC), Methyl hydroxyethyl cellulose, Ethylcellulose, Povidone, etc, while the commonly used enteric coating polymers are Cellulose acetate phthalate, Acrylate polymers (Eudragit L& Eudragit S), HPMC phthalate, etc. An ideal film coating material should possess the following characteristics [2]:

- It should be soluble in a solvent of choice.
- It must produce an elegant coat.
- It should be stable in presence of heat, light or moisture.
- It should not possess disagreeable color, taste or odor.
- It should be non-toxic and pharmacologically inert.
- It should be compatible with coating additives.

Organic film coating

Currently, the most common technology for coating solid dosage forms is the liquid coating technology (aqueous based organic based polymer solutions). In liquid coating, a mixture of polymers, pigments and excipients is dissolved in an organic solvent (for water insoluble polymers) or water (for water soluble polymers) to form a solution, or dispersed in water to form a dispersion, and then sprayed onto the dosage forms in a pan coater (for tablets) and dried by continuously providing heat, typically using hot air, until a dry coating film is formed [4]. Organic solvent based coating provides a variety of useful polymer alternatives, as most of the polymers are soluble in the wide range of organic solvents. However, there are certain disadvantages like they are flammable, toxic, and costly and possess environmental issues [5]. ICH guidelines also prefer the avoidance of organic solvents in pharmaceutical dosage formulations considering products safety profile. So, Pharmaceutical industries are now paying much attention in developing formulations with aqueous film coating.

Aqueous film coating

All above problems with organic solvents resulted in shift to use of water as the preferred coating solvent. Aqueous-based coatings have been increasingly used compared with organic-based coatings. The conversion from organic solvent based coating to aqueous based coating makes the coating process more economical, though initially it may need a little investment to upgrade the coating facility.

The need of this up-gradation arises due to the need of higher drying capacity (the latent heat of water is 2200kJ as compared to 550kJ for methylene chloride). This implies that one would require 4 times more energy as compared to organic solvent [5].

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).

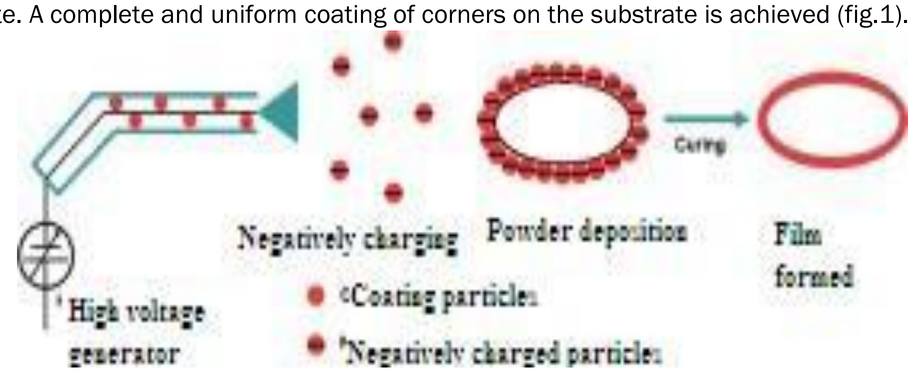

Figure1: Mechanism of electrostatic coating [6].

There are two kinds of spraying units, based on the charging mechanism a) corona charging and b) tribo charging.

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.

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 [7,8,9,10].

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. 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).

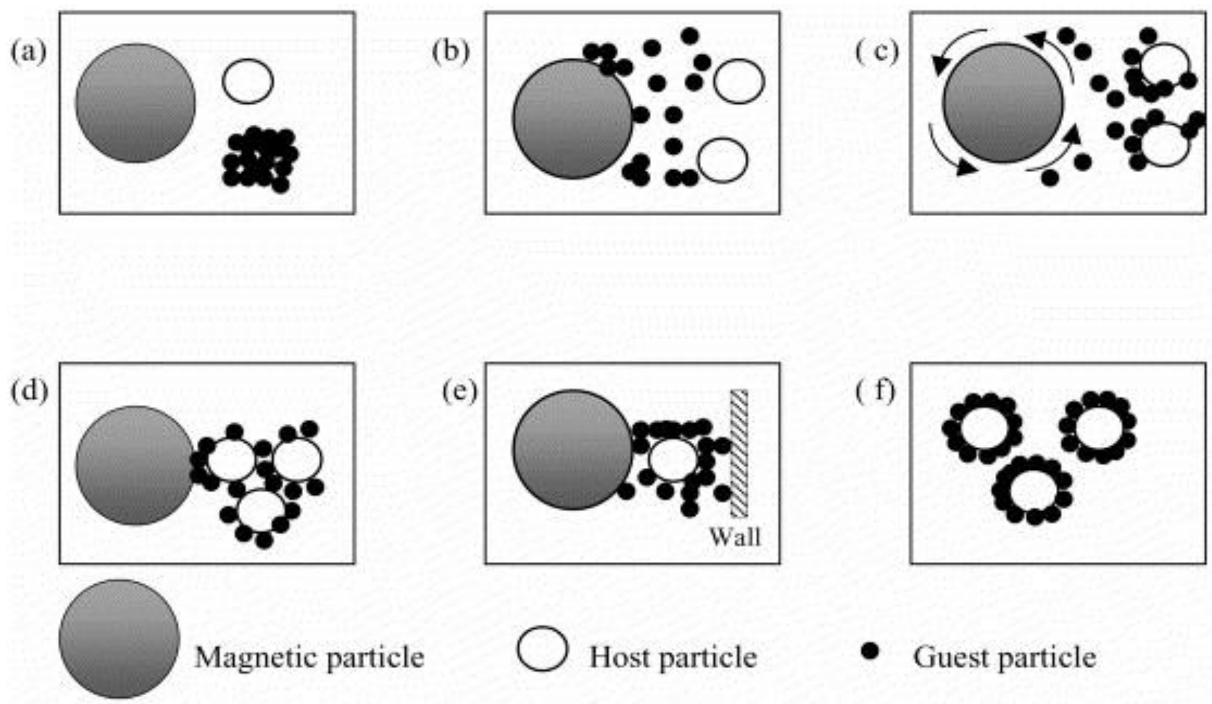

Figure 2: Mechanism of coating in the MAIC process: (a) excitation of magnetic particle, (b) de-agglomeration of guest particles, (c) shearing and spreading of guest particles on the surface of the host particles, (d) magnetic–host–host particle interaction, (e) Magnetic–host–wall interaction and (f) coated products [11].

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 [12, 13].

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 [2].

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 [2].

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 [2].

Defects and Solutions of coated tablets

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.

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.

Erosion

This can be the result of soft tablets, an over-wetted tablet surface, inadequate drying, or lack of tablet surface strength.

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.

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.

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.

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.

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 [14, 15].

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 [2, 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.

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