



TABLET COATING TECHNIQUES: CONCEPTS AND RECENT TRENDS

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Article Received on: 18/07/12 Revised on: 10/08/12 Approved for publication: 01/09/12

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ABSTRACT

Tablet coating is a common pharmaceutical technique of applying a thin polymer-based film to a tablet or a granule containing active pharmaceutical ingredients (APIs). Solid dosage forms are coated for a number of reasons, the most important of which is controlling the release profiles. 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. There are various techniques for tablet coating such as sugar coating, film coating, and enteric coating. Recent trends in pharmaceutical technologies are the development of coating methods which overcomes the various disadvantages associated with solvent based coatings. In these latest technologies coating materials are directly coated onto the surface of solid dosage forms without using any solvent. Various solventless coatings are available such as electrostatic dry coating, magnetically assisted impaction coating, compression coating, hot melt coating, powder coating, and supercritical fluid coating. Supercell Coating Technology is a revolutionary tablet coating that accurately deposits controlled amounts of coating materials on tablets even if they are extremely hygroscopic or friable. Magnetically assisted impaction coating, electrostatic dry coating in solventless coatings, aqueous film coating and Supercell coating technology are also available recent technique of coating. An ideal tablet should be free from any visual defect or functional defect. The advancements and innovations in tablet manufacture have not decreased the problems, often encountered in the production, instead have increased the problems, mainly because of the complexities of tablet presses; and/or the greater demands of quality. This review deal in detail about history, recent tablet coating technique and remedies associated with the tablet coating.

Keywords: - Tablet, Coating, History of coating, Supercell Coating, Magnetically Assisted Impaction Coating

INTRODUCTION

Tablet is a pharmaceutical solid dosage form, comprising 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. Coating is a process by which an essentially dry, outer layer of coating material is applied to the surface of a dosage form to achieve specific benefits. 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 pans¹. Many solid pharmaceutical dosage forms are produced with coatings, either on the external surface of the tablet, or on materials dispensed within gelatine capsules. The tablet should release the medicament gradually and the drug should be available for digestion. The coating process can be specially formulated to regulate how fast the tablet dissolves and where the active drugs are to be absorbed into the body after ingestion².

PRIMARY COMPONENTS INVOLVED IN TABLET COATING

- 1) Tablet properties
- 2) Coating process, design and control

Coating equipments

Parameters of the coating process

Facility and ancillary equipments

Automation in coating processes.

Tablet Properties

Tablets that are to be coated must possess some proper physical characteristics. The tablets roll in a coating pan. To tolerate the intense attrition of tablets striking other tablets or

walls of the coating equipment, the tablets must be resistant to abrasion and chipping.

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. Rotating coating pans are often used in the pharmaceutical industry. Uncoated tablets are placed in the pan 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. The coating process is usually consisting of the following steps:

- a. Batch identification and Recipe selection (film or sugar coating)
- b. Loading/Dispensing (accurate dosing of all required raw materials)
- c. Warming
- d. Spraying (application and rolling are carried out simultaneously)
- e. Drying
- f. Cooling
- g. 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

Benefits of Tablet Coating

Tablets coating mask the taste, odour, or colour of the drug. Tablets coating control the release of the drug from the tablet. It provides physical and chemical protection and protects the drug from the gastric environment of the stomach (acid resistant enteric coating). Incorporate of another drug or formula adjuvant in the coating to avoid chemical incompatibilities or to provide sequential drug release, improvement of pharmaceutical elegance by use of special colours and contrasting printing can also be obtained from tablet coating.

Shortcomings of Tablet Coating

Sugar coating carries relatively high cost, long coating time and high bulk due to the use of other coating materials. It is tedious, time-consuming and requires the expertise of highly skilled technician³.

HISTORY OF COATING TECHNIQUE

“Panning” was the original word for the process of adding a coating to a tablet. The word panning is still a common term which is used in the confectionary business. In past years coating perform basically using a rotating drum (pan) on a stand. A coating solution was added, while the rotation of the pan distributed the solution throughout the bed of tablets. The main disadvantage of this technology was slow waiting for the coating solution to dry; and the trick was to get it to dry evenly. With the advent of film coating a film or thin membrane, usually representing 1-3% of the total tablet weight, was sprayed on using a perforated pan. To decrease the overall process time, holes were made through the pan so that treated air (hot or cold) could be pulled through the pan, much like a clothes dryer, allowing the tablets to dry more quickly. With this advent of improved drying came the ability to switch the film coating solution from a solvent based solution to a water based solution⁴.

Coating of pharmaceutical dosage forms has been practiced for many centuries²⁰. The historical development of coating technique is mentioned below:-

LAST 40 YEARS:-

Features

- Introduction of the side-vented tablet coating pans (with perforations), Figure 1,
- Evolution was required for the introduction of aqueous based film coating polymers to the pharmaceutical industry
- Carbon steel construction except for pan
- Many screws, not welded in places
- Does not complies GMP



Figure 1. Side vented tablet coating pans

LAST 30 YEARS:-

Introduction of reliable microprocessor based process control systems required to insure process control and repeatability.

Features

- Improved design spray nozzles for tablet coating
- specific applications (all stainless steel)
- Improved air preparation systems required for consistent aqueous process drying
- Improved GMP coater design, more cleanable, all stainless steel (Figure 2)
- Improved tablet handling
- All required for the optimization of aqueous film coating process



Figure 2. Reliable microprocessor based process control system

LAST 20 YEARS:-

Features

- Potable water storage tank.
- Washing nozzles (coater mounted).
- Reduced cleaning time
- Cleaning of the areas, that are difficult to access
- Conservation of cleaning solution
- Standardization of the cleaning process
- Energy conservation (As shown in Figure 3)



Figure 3. Advanced automatic Coating in Place (CIP) and Washing in Place (WIP) systems

LAST 10 YEARS

- More advanced film coating spray nozzles with anti-bearding designs
- More reliable industrial automation for accurate and repeatable control of process parameters ie: dewpoint, mass solution flow, air flow etc.
- The evolution of the improvements to the batch tablet coater has allowed the recent advancements in continuous tablet coating (Figure 4).

Figure 4. More advanced automation in Coating System⁵**TRADITIONAL COATING TECHNIQUES:-**

Generally three methods are used for tablet coating

1. SUGAR COATING
2. FILM COATING
3. ENTERIC COATING

SUGAR 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 the tablet size and 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 gloss³.

The characteristics of sugar coating technique has been given below (Table 1)

FILM COATING:-**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?

Ideal requirements of film coating materials:

- 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 procedure³

There are various materials used in film coating as shown in table no. 2. Table no. 3 summarizes the characteristics of film coating.

Table No. 1:- Characteristic of Sugar Coating

| Type | CHARACTERISTIC | SUGAR COATING |
|---------|---|--|
| Tablet | Appearance | Rounded with high degree of polish |
| | Weight increase because of coating material | 30-50% |
| | Logo or 'break lines' | Not possible |
| Process | Operator training required | Considerable |
| | Adaptability to GMP | Difficulty may arise |
| | Process stages | Multistage process |
| | Functional coatings | Not usually possible apart from enteric coating ⁶ |

Table No. 2: Materials Used in Film Coating

| S. No. | Material | Type | Uses | Examples |
|--------|--------------------|----------------------------|---|---|
| 1. | Film Former | Enteric Non Enteric | To control the release of drug | Hydroxy Propyl Methyl Cellulose (HPMC), Methyl Hydroxy Ethyl Cellulose (MHEC) |
| 2. | Solvents | ----- | To dissolve or disperse the polymers | IPA and Methylene chloride |
| 3. | Plasticizer | Internal Plasticizing | It Pertains to the chemical modification of the basic polymer that alters the physical properties of the polymer. | Glycerol, Propylene glycol, PEG 200-6000 Grades |
| | | External Plasticizing | It incorporated with the primary polymeric film former, changes the flexibility, tensile strength, or adhesion properties of the resulting film | Diethyl phthalate (DEP), Dibutyl phthalate (DBP) and Tributyl citrate (TBC) |
| 4. | Colourants | Inorganic materials | For light shade: concentration of less than 0.01% may be used | Iron Oxides |
| | | Natural coloring materials | For dark shade: concentration of more than 2.0% may be required. | Anthocyanins, Caramel, Carotenoids, |
| 5. | Opacuant-Extenders | ----- | Formulations to provide more pastel colours and increase film coverage | Titanium dioxide, silicate (talc & aluminum silicates), carbonates(magnesium carbonates) ³ |

Table No. 3:- Characteristic of Film Coating

| Type | CHARACTERISTIC | FILM COATING |
|---------|---|---|
| Tablet | Appearance | Retain contour of original core. Usually not as shiny as sugar coat type |
| | Weight increase because of coating material | 2-3% |
| | Logo or 'break lines' | Possible |
| Process | Operator training required | Process tends itself to automation and easy training of operator |
| | Adaptability to GMP | High |
| | Process stages | Usually single stage |
| | Functional coatings | Easily adaptable for controlled release ⁶ |

ENTERIC COATING :-

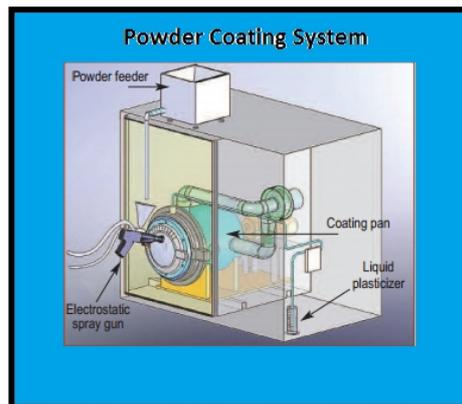
- Ideal Properties of Enteric Coating Materials:-
- Resistance to gastric fluids.
- Susceptible/permeable to intestinal fluid.
- Compatibility with most coating solution components and the drug substrate.
- Formation of continuous film.
- Nontoxic, cheap and ease of application.
- Ability to be readily printed.

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^{3,19}

RECENT TRENDS IN TABLET COATING TECHNIQUES:-**ELECTROSTATIC DRY COATING:**

An electrostatic dry powder coating process for tablets was developed for the first time by electrostatic dry powder coating in a pan coater system (Figure 5). The optimized dry powder coating process produces tablets with smooth surface, good coating uniformity and release profile that are comparable to that of the tablet cores. This novel electrostatic dry powder coating technique is an alternative to aqueous or solvent based coating process for pharmaceutical products⁸.

Figure 5. Electrostatic Powder Coating System⁷

The electrostatic coating process is widely useful in food technology, paint technology, metal coatings, coating of living cells and coating of tablets as well as capsules. The principle of electrostatic powder coating states that spraying of a mixture of finely grounded particles and polymers onto a substrate surface without using any solvent and then heating the substrate for curing on oven until the powder mixture is fused into film (Figure 6)⁹.

According to the charging mechanism, there are two types of spraying units:

- a) Corona charging
- b) Tribo charging.

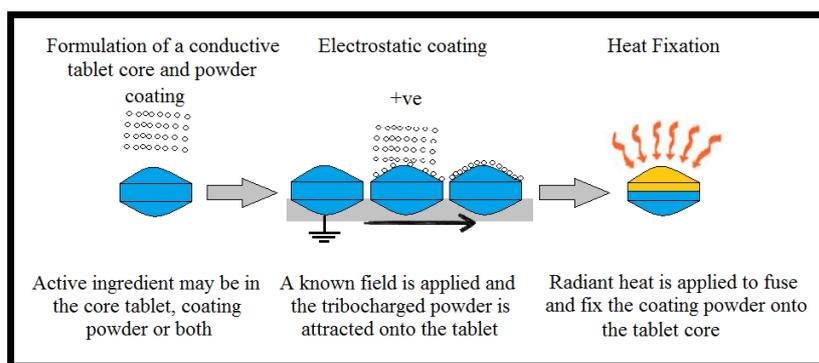


Figure 6: Schematic diagram of electrostatic dry coating.

Mechanism of Corona charging:

In this mechanism, the electrical breakdown and 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 substrate and the charging gun is done by the combination of electrical and mechanical forces. The mechanical forces generated by the air blows the powder towards the substrate from the spray gun. The electrical forces are derived from the electrical field between the earthen substance and the charging tip of the spray gun, and from the repulsive forces between the charged particles. The electrical field can be

adjusted to direct the powder's flow, control pattern size, shape, and powder density as it is released from the gun.

Mechanism of tribo charging:

In the tribo charging, it makes the use of the principle of friction charging associated with the dielectric properties of solid materials and so that no free ions and electrical field will be present between the spray gun and grounded substance. For tribo charging guns, the electrical forces are only regarded to the repulsive forces between the charged particles. After spraying, charged particles come into the space adjacent to the substrate and the attraction forces between the grounded substrate and the charged particles makes the particle to deposit on the substrate. Charged

particles are sprayed uniformly onto the earthen substrate in virtue of mechanical forces and electrostatic attraction. Particles deposit on the substrate before the repulsion force of the deposited particles against the coming particles increase and exceed the electrostatic attraction. Finally once the repulsion force becomes equivalent to the attraction force, particles cannot adhere to the substrate any more, and the coating thickness does not increase any more. Electrostatic dry coating of electrically non-conducting substrates and pharmaceutical tablet cores is more difficult. For secure the coating to the core, the powder must be transformed into a film without damaging the tablet core, which usually includes organic materials. In addition, an even coating is required and it is difficult to obtain an even coating of powder on a tablet core. Various properties of powder such as particle size distribution, chemical composition, tribo and corona charging characteristics, electrical resistivity, hygroscopicity, fluidity and shape distribution play significant role on the performance of powder coating such as transfer efficiency, film thickness, adhesion and appearance. Distance, nozzle geometry, and composition of the precursor solution play an important role in the electrostatic coating process.

Phoqus is a leading-edge drug delivery company which is providing a range of innovative and patented drug delivery systems based on electrostatic dry powder coating technology. There are several patents on the design of apparatus which are used for electrostatic coating of powders onto the pharmaceutical dosage forms. Most of these apparatus are patented by Phoqus pharmaceuticals limited⁹. There are several patents which provide the various coating compositions for the electrostatic coating as mentioned in table no. 4

Table No 4:- Patents for Electrostatic Coating of Phoqus Pharmaceuticals

| Patent Number | Title Of Patent | Date Issued |
|---------------|---|-------------------------------|
| 6783768 | Method and apparatus for the coating of substrates for pharmaceutical use | August 31, 2004 |
| 7008668 | Powder coating composition for electrostatic coating of pharmaceutical substrates | March 7, 2006 |
| 7070656 | Electrostatic coating | July 4, 2006 |
| 7144597 | Electrostatic application of powder material to solid dosage forms utilizing an electrically con | December 5, 2006 |
| 7153538 | Method and apparatus for the coating of substrates for pharmaceutical use | December 26, 2006 |
| 7285303 | Powder material for electrostatic application to a substrate and electrostatic application of the powder material | October 23, 2007 |
| 7384661 | Electrostatic application of powder material to solid dosage forms in an electric field | June 10, 2008 ¹⁰ . |

MAGNETICALLY ASSISTED IMPACTION COATING (MAIC):

A Technique is developed for estimating the coating time in a magnetically assisted impaction coating (MAIC) device. The mixture of the host, guest and magnetic particles is assumed to stay in a fluidized state where the distribution of velocities is a Maxwell-Boltzman type. It is assumed that the collisions occurs among the particles are important for impinging the guest particles onto the surface of host particles, and thus forming a semi-permanent coating on the surface of host particles. The coating time is depend on several parameters, including the number density of host particles, the diameter ratio of the host and guest particles, the height of the fluidized particle bed and the material properties of the host and guest particles. There is an optimal value of the bed height for which the coating time is a minimum. The coating

time increases sharply when the bed height is smaller or larger than the optimal value, and also when the diameter of host particles is increased¹¹.

Various 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 shearing stresses or high impaction forces or exposure to higher temperature for 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 foods and pharmaceutical ingredients, being organic and relatively very soft, are very sensitive to heat and can quite easily be deformed by severe mechanical forces. Hence, some 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 build up of heat are the best candidates for such applications. The magnetically assisted impaction coating (MAIC) devices can coat soft organic host and guest particles without changing in the material shape and size. Although there is some heat generated on a minute level due to the collisions of particles during MAIC, but it is negligible. This is an additional advantage when dealing with temperature sensitive powders such as pharmaceuticals⁹.

Magnetically Assisted Impaction Coating (MAIC) is being developed to improve the effectiveness of mixing powders with nano-sized particles without the aid of a solvent or heat. In general, uniform mixing of nano-sized materials is more difficult than mixing of larger sized materials. Still in development, the technology will aid manufacturing applications in producing higher quality products¹².

Mechanism of coating in the MAIC process:

There are few stages in the mechanism of coating of MAIC process is

Stage-I: Excitation of magnetic particles.

Stage-II: De-agglomeration of guest particles (coating material).

Stage-III: Shearing and spreading of guest particles on the surface of the host particles (material to be coated).

Stage-IV: Magnetic-host-host particle interaction.

Stage-V: Magnetic-host-wall interaction. and

Stage-VI: Formation of coated products.

Apparatus for MAIC:

MAIC apparatus consist of processing vessel surrounded by the series of electromagnets connected to the alternating current. The host and guest materials are placed in the vessel and added the measured mass of the magnetic particles. The magnetic particles are made of barium ferrite and they are coated with polyurethane to prevent contamination of the coated particles. When a magnetic field is present, the magnetic particles are agitated and move frequently inside the vessel, resembling a fluidized bed system. These agitated magnetic particles then impart energy to the host particles and guest particles, causing collisions and allowing coating to be achieved by means of impaction or peening of the guest particles onto the host particles (Figure 7). The magnetic particle motion studies suggests that the primary motion due to the magnetic field is the spinning of the magnetic particles, promoting de- agglomeration of the guest particles as well as the spreading and shearing of the guest particles onto the surface of the host particles. However, the effect of the translational speed is also significant as it allows for the impaction of one particle onto another, promoting coating. The parameters must be considered during MAIC are particle

size of guest particles and host particles, guest to host size ratio, magnetic to host size ratio, processing time, current or voltage and frequency, magnet to powder mass ratio, current and frequency, magnetic particle speed etc

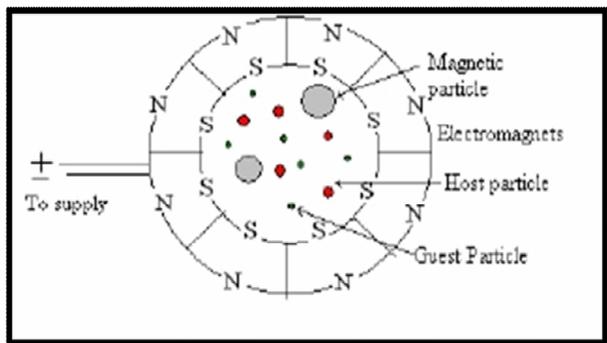


Figure 7:- Schematic diagram of MAIC

Ramlakhan M. et al. (2000) conducted an experiment to evaluate the effectiveness of the MAIC device in modifying the surface properties of cornstarch and cellulose (host particles) when they are coated with silica (guest particles). It was observed that very large agglomerates of silica were broken up into smaller primary sizes (de-agglomeration) during the MAIC process and soft organic materials (cornstarch and cellulose) get coated maintaining almost their original shape and size. The number of guest particles (coating particles) on the surface of the host particles (particles to be coated) has only a minor effect on the flowability once the cohesion force is reduced by one or more coating particles and hence even with a very discrete coating on the surface of the host particle there is a significant improvement in the flowability of the material. Similar study was done by Raizza R (2006) where the coating of ibuprofen with two different Silica, R 972 and EH-5 is done to increase its flowability. When the primary guest particles are in the sub-micron range, the attraction forces Van der Waals, electrostatic etc. among the primary particles are relatively very strong and require larger forces to separate them. Smaller host particles can obtain larger velocities than larger host particles from collisions with the magnetic particles, resulting in higher forces of impaction, sufficient to break the agglomerated guest particle structure. Yang J. et al. (2005) observed that the reduction in the cohesion force for the coated particles is inversely proportional to the size ratio of the guest particles and the host particles, indicating that smaller guest particles provide a larger reduction in the cohesive force. According to Singh P. et al (2001) model, the coating time in the MAIC device depends on the density of host particles, the diameters of the host and guest particles, the initial and final bed heights, and the material properties of the host and guest particles. Also there is an optimal value of the bed height for which the coating time of the host particle is a minimum. The coating time increases sharply when the bed height is smaller or larger than the optimal value, and also when the diameter of host particles is increased. This model also suggests that the coating time decreases when the initial bed height is increased and also when the ratio of host and guest particle diameters is reduced^{9,23}.

AQUEOUS FILM COATING TECHNOLOGY

The sugar coating process is very time consuming and it is depending on the skills of coating operator, this technique has been replaced by film coating technology. This technique was started with the use of organic solvents like methylene

chloride but now has been replaced with aqueous film coating due to environmental and regulatory considerations. Moreover the cost of any organic solvent is far more than the cost of purified water. Therefore, the conversion from organic solvent based coating to aqueous solvent based coating makes the coating process more economical, though initially it may need a little more investment to upgrade the coating facility. The need of this upgradation arises due to the need of higher drying capacity (the latent heat of water is 2200 kJ as compared to 550 kJ for methylene chloride which implies that to evaporate water one will need 4 times more energy as compared to methylene chloride)¹². The figure of enteric aqueous film coating tablets has been shown in figure 8.



Figure 8:- Enteric aqueous film coating tablets

The problems associated with organic solvent-based film coating and the advantages of aqueous based systems have long been recognized. Film coating technology has now advanced to the level where aqueous coating has become a matter of routine coating rather than the exception. The successful introduction of a wide variety of aqueous based film coating products (by M/s. Ideal Cures Pvt. Ltd., under the brand name INSTACOAT) has resulted in easy conversion from organic solvent based coatings to aqueous film coating for several companies; many of them still use the conventional coating equipment.

Development of film coating formulation

The optimization of film coating formulation may be necessary to improve adhesion of the coating to the core material, to decrease bridging of intagliations, to increase coating hardness or to improve any other property that the formulator deems deficient. The development scientist has to consider three major factors which can affect the film quality - tensile strength of the film coating formulation (mainly dependant on polymer properties), elasticity of the resultant film (mainly dependant on properties and quantity of plasticizer used) and the film-tablet surface interaction (each and every ingredient used in the coating formulation can affect this interaction and can change the adhesion properties of the film on the tablet surface). Due to these important factors, it becomes very important to use the most optimized coating formulations in order to get the best results¹³.

SUPERCELL COATING TECHNOLOGY:-

Supercell Coating Technology is a revolutionary tablet coating that accurately deposits controlled amounts of coating materials on tablets—even if they are extremely hygroscopic or friable. Inconsistent and imperfect condition, this “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, intagliations can get filled in by coating material, and edges and corners may not be coated with the same thickness as the tablet faces. The inaccuracy in deposition of coating material limits the use of modified

release coatings (figure 9). In a laboratory, it is necessary to coat several kilograms of tablets at one time, making R&D of a tablet dosage form costly and difficult.



Figure 9:- Supercell Coating Technology

Furthermore, extremely hygroscopic tablets cannot be coated with current technology, nor can flat or other odd shapes be consistently coated. This process must be run slowly to prevent "twinning," where two or more tablets stick together. Tablets may also be coated in a Wurster-type coating apparatus, but tablet attrition generally prevents all but the hardest tablets from being coated this way¹⁴.

The aim of this study is to investigate the nature of Supercell coating, an on-line tablet coater that employed a unique pattern of airflow. Tablets coated at different spray rates (4, 6, 8, 10, and 12 mL/min) are analyzed to investigate the influence of different wetting conditions on the quality of coats formed. At a spray rate of 6 mL/min, surface roughness is found to be lower than at the other spray rates, and the coat appears smoothest, whereby droplets seem fused together. At higher spray rates, the droplets appear as branching arms and scale-like structures¹⁵.

SUPERCELL™ Coating Technology

(SCT) is an invention of Niro Pharma Systems effectively solving all of these problems using a small, modular design.

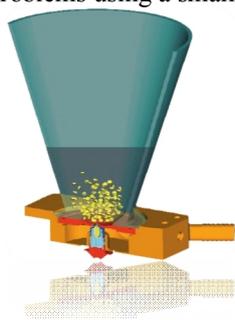


Figure 10:- Processing of Coating Technology

SCT's continuous small-batch capable coating process is predictable and efficient. In SCT, the tablets are coated in batches ranging from 30 to 120 grams, which linearly scale up to production capacities. The tablets are coated with the coating spray in the same direction as the drying gas, which results in a more efficient process (Figure 10). Due to SCT's unique air distribution plate design, the tablets move very quickly and predictably through the spray zone, receiving only a small amount of coating per pass, and therefore achieving higher coating accuracy. The process time is short, in seconds or in minutes as opposed to hours, and therefore gentler on the tablets¹⁴.

Niro Company claims that conventional methods of tablet coating have inconsistent and imperfect results, which leads to non-regular results that can affect the behaviour of the tablet. This result can impart an element of variability that gains in significance if a small run of tablets is being produced for clinical trials. In conventional coaters, coating tablets are loaded in large rotating pans and vented for hot air drying, but this means tablet edges can get ground off, intagliations can get filled in by coating material and edges and corners may not be coated with the same thickness as the tablet faces. These types of inaccuracies limit the use of modified release coatings, according to Niro¹⁶.

SUPERCELL™ Coating Technology may also be used for coating of friable tablets, as well as flat or highly oblong tablet shapes. In this process, drying is very fast, making it possible to coat extremely hygroscopic tablets. The accuracy of deposition is highly enough that Active Pharmaceutical Ingredients can be layered 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

1. Continuous coating
2. Short processing time
3. Flexible modular design
4. No scale-up to parameters
5. Production capacity of 6 cells coats 200K tph of 120 mg tablets
6. R&D batch size (Minimum batch size of 30 grams)
7. Enhancing technology
8. Multi-layer coating
9. Difficult-to-coat shapes
10. Friable tablets
11. "Low humidity process" suitable for moisture sensitive materials
12. Enabling technology
13. Accuracy of coating (RSD less than 1% demonstrated)¹⁴.

TABLET COATING DEFECTS

An ideal tablet should be free from any visual defect or functional defect. The advancements and innovations in tablet manufacture have not decreased the problems, often encountered in the production, instead have increased the problems, mainly because of the complexities of tablet presses; and/or the greater demands of quality. An industrial pharmacist usually encounters a number of problems during manufacturing. Majority of visual defects are due to inadequate fines or inadequate moisture in the granules ready for compression or due to faulty machine setting. Functional defects are due to faulty formulation. Solving many of the manufacturing problems requires an in-depth knowledge of granulation processing and tablet presses, and is acquired only through an exhaustive study and a rich experience^{17,18,25}. Here, we will discuss the imperfections found in tablets along-with their causes and related remedies (see table no. 5). Several tablets are being shown in figure no. 11. The imperfections are known as: 'VISUAL DEFECTS' and they are either related to imperfections in anyone or more of the following factors:

Table No. 5: Tablet Coating Defects with Reason and Their Remedies

| S. No. | Tablet defects | Definition | Reason | Remedies |
|--------|-----------------------|---|--|---|
| 1. | Blistering | It is local detachment of film from the substrate forming blister. | Entrapment of gases in the film due to overheating either during spraying or at the end of the coating run. | Milder drying conditions are warranted in this case. |
| 2. | Chipping | It is defect where the film becomes chipped and dented, usually at the edges of the tablet. | Decrease in fluidizing air or speed of rotation of the drum in pan coating | Be careful not to over-dry the tablets in the preheating stage. That can make the tablets brittle and promote capping. |
| 3. | Picking | It is defect where isolated areas of film are pulled away from the surface when the tablet sticks together and then part. | Conditions similar to cratering that produces an overly wet tablet bed where adjacent tablets can stick together and then break apart. | A reduction in the liquid application rate or increase in the drying air temperature and air volume usually solves this problem. Excessive tackiness may be an indication of a poor formulation. |
| 4. | Twinning | This is the term for two tablets that stick together | common problem with capsule shaped tablets. | Assuming you don't wish to change the tablet shape, you can solve this problem by balancing the pan speed and spray rate. Try reducing the spray rate or increasing the pan speed. In some cases, it is necessary to modify the design of the tooling by very slightly changing the radius. The change is almost impossible to see, but it prevents the twinning problem. |
| 5. | Pitting | It is defect whereby pits occur in the surface of a tablet core without any visible disruption of the film coating. | Temperature of the tablet core is greater than the melting point of the materials used in the tablet formulation. | Control the temperature of tablet core during the formulation |
| 6. | Cratering | It is defect of film coating whereby volcanic-like craters appears exposing the tablet surface. | The coating solution penetrates the surface of the tablet, often at the crown where the surface is more porous, causing localized disintegration of the core and disruption of the coating. | ----- |
| 7. | Blooming | It is defect where coating becomes dull immediately or after prolonged storage at high temperatures. | It is due to collection on the surface of low molecular weight ingredients included in the coating formulation. In most circumstances the ingredient will be plasticizer. | ----- |
| 8. | Blushing | It is defect best described as whitish specks or haziness in the film. | It is thought to be due to precipitated polymer exacerbated by the use of high coating temperature at or above the thermal gelation temperature of the polymers. | ----- |
| 9. | Colour variation | A defect which involves variation in colour of the film. | Alteration of the frequency and duration of appearance of tablets in the spray zone or the size/shape of the spray zone. | A reformulation with different plasticizers and additives is the best way to solve film instabilities caused by the ingredients |
| 10. | Cracking or Splitting | It is defect in which the film either cracks across the crown of the tablet (cracking) or splits around the edges of the tablet (Splitting) | Internal stress in the film exceeds tensile strength of the film. | tensile strength of the film can be increased by Using higher molecular weight polymers or polymer blends |
| 11. | Infilling | It is defect that renders the intagliations indistinctness. | Inability of foam, formed by air spraying of a polymer solution, to break. The foam droplets on the surface of the tablet breakdown readily due to attrition but the intagliations form a protected area allowing the foam to accumulate and "set". Once the foam has accumulated to a level approaching the outer contour of the tablet surface, normal attrition can occur allowing the structure to be covered with a continuous film. | Judicious monitoring of the fluid application rate and thorough mixing of the tablets in the pan can prevent filling. |
| 12. | Orange peel/Roughness | It is surface defect resulting in the film being rough and nonglossy. Appearance is similar to that of an orange. | Inadequate spreading of the coating solution before drying. | 1. Thinning the solution with additional solvent may correct this problem. 2. Moving the nozzle closer to the tablet bed and reducing the degree of atomization can decrease the roughness due to "spray drying". |
| 13. | Mottling | Mottling is uneven distribution of the colour on the surface of the tablet, with dark and light patches on it. | It is mainly due to different colouration of the excipient or the degradation product of the tablet is coloured. | Coating solution prepare properly in sufficient quantity ^{17-18,21} . |



Figure No. 11: Pictorial Representation of Tablet Defects

CONCLUSION

In recent decades, coating of pharmaceutical dosage forms has been subject of remarkable developmental efforts aiming to ensure and enhance the quality of tablet dosage form. Magnetically assisted impaction coating and electrostatic dry coating avoids major disadvantages of solvents based coating. Methods produce uniform coating but only with specialized instrumentation. Electrostatic dry coating requires special type of powder coating composition. Electrostatic dry coating enables coating of tablet with different colours on either side along-with printing on tablet on pharmaceutical dosage form. Safety aspects of these coatings in humans is still to be unveiled thus further research in health and safety aspects of these technologies will ensure the commercialization of these technologies in pharmaceutical industry. Improvements regarding particle movement, heat and energy transfer, film distribution, drying efficiency and continuous processing have contributed to significantly develop this technology. However evaluation and success of further constructional improvements in coating methods appear to depend on accurate analytical tools and advanced methods for process modelling and control. In this regard, achieving optimal manufacturing efficiency and high product quality still remains a major challenge for future research.

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Source of support: Nil, Conflict of interest: None Declared