

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Appraisal On: Tablet Coating and Its Outcome with Complementary Sprouting Technology.

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ABSTRACT

Tablet coating is the key step involved in the manufacturing of tablets having controlled release, delayed release profiles. The tablet coating have number of advantages like masking odor, taste, color of the drug, providing physical and chemical protection to drug, Protecting drug from the gastric environment. Tablets are usually coated in horizontal rotating pan with coating solution is either directly poured or sprayed on to them. The amount of coating on the surface of a tablet is critical to the effectiveness of the oral dosage form. Recent trends in tablet coating focuses on overcoming disadvantage of solvent based coating. This review concerns with the coating process, equipments involved, coated tablets evaluation and specialized coating techniques. 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: Coating, Pan, Coating Solution, Controlled Release,

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INTRODUCTION

Tablet coating can be described as a process of applying an edible paint on the surface of 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].

NECESSITY OF TABLET COATING

A number of reasons can be suggested as follows

- The core contains a material which has a bitter taste in the mouth or has an unpleasant odour.
- Coating will protect the drug from the surroundings with a view to improve its stability.
- Coating will increase the ease by which a tablet can be ingested by the patient.
- Coating will develop the mechanical integrity; means coated products are more resistant to mishandling (abrasion, attrition, etc.).
- The core contains a substance which is incompatible in the presence of light and subject to atmospheric oxidation, i.e. a coating is added to improve stability.
- The core alone is inelegant. The active substance is colored and migrates easily to stain hands and clothes.
- The coated tablets are packed on high-speed packaging machine.
- Coating reduces friction and increases packaging rate.
- Coating can modify the drug release profile, e.g., enteric coating, osmotic pump, pulsate delivery [3-5].

BASICS PRINCIPLES INVOLVED 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

- Solution in which influences the release pattern as a little as possible and does not markedly change the appearance.
- Modified release with specific requirement and release mechanism adapted to boy function in the digestive tract.
- Color coating which provides insulation.
- To incorporate another drug or formula adjuvant in the coating to avoid chemical incompatibilities or to provide sequential drug release.

THERE ARE TWO PRIMARY COMPONENTS OF TABLET COATING

1. Tablet properties
2. Coating process
3. Coating equipments
4. Parameters of the coating process

TABLET PROPERTIES

- Tablet must be resistant t abrasion and chips
- The ideal shape of the tablet for coating is sphere.
- The harness of the tablet should be less than 5 kg/cm^2 .
- The tablets must have god friability.
- Tablets must have good flow.

- To tolerate the intense attrition of tablet striking other tablets or the walls of Coating equipment, the tablets must be resistance to abrasion and chipping.
- Tablet Surfaces that are brittle, Soften in the presence of heat are unacceptable for film coating.

COATING PROCESS

The basic principle of tablet coating is simple. Tablet coating is an application of coating composition to a moving bed of tablets with the concurrent use of heated air to facilitate evaporation of the solvent. The distribution of coating is accomplished by the movement of the tablets either perpendicular (coating pan) or vertical (air suspension).

COATING EQUIPMENTS

For the coating process there are 3 types of following equipments.

- Conventional coating pan.
- The perforated coating pan.
- The fluidized bed coater.

CONVENTIONAL COATING PAN SYSTEMS

- Pellegrini system
- Immersion-sword system
- Immersion –tube system

Conventional coating pan system

Improvements in conventional pan are pellegrini system which has a baffled pan and diffuser (shown in fig.1). The immersion sword system and the immersion tube system all of them have enhanced drying efficiency compared to older models. The newer models are completely enclosed.

The standard coating pan system consists of a circular metal pan mounted somewhat angularly on a stand. The pan is 8-60 inches diameter and is rotated on its horizontal axis by a motor. Heated air is directed into the pan and onto the tablet bed surface, and is exhausted by means of ducts positioned through the front of the pan [6-9].

Pellegrini pan

1. Has a baffled pan and diffuser for uniform distribution of drying air.
2. It is enclosed and automated.

Immersion-sword system

1. Drying air is introduced through a perforated metal sword immersed in the tablet bed.
2. The drying air flows upward through bed. (shown in fig.2)
3. Coating solutions are applied by an atomized spray system directed onto the tablet bed surface.

Immersion-tube system

1. The tube immersed delivers heated air
2. Coating solution is applied through spray nozzle built in the tip of tube. (shown in fig. 3)
3. The drying air flows upward through the tablet bed and is exhausted by a conventional duct.

Coating Pans Systems

1. Accela-coata

2. Driacoater
3. Glatt coater
4. Fluid Bed Systems

Accela-Coata and Hi-coater system

Drying air is directed in to drum, is passed through bed, and is exhausted through perforations in to drum. (Shown in fig.4, 6)

a) Driacoater:

1. Introduces drying air through hollow perforated ribs located inside periphery of the drum.
2. As the coating pan rotates, ribs dip into tablet bed. (shown in fig.5)
3. Drying air passes up through and fluidizes the tablet bed.

b) Glatt coater

1. Drying air is directed from inside the drum through the tablet bed and out an exhaust duct
2. It consists of an optional split-chambered plenum, drying air can be directed in the reverse manner up through the drum perforations for partial fluidization of the tablet bed.
3. Several air flow configurations are possible.

c) Fluidized bed coating system (Air suspension system)

1. These are highly efficient drying systems.
2. Fluidization of tablet bed is achieved in a columnar chamber by the upward flow of drying air.
3. The airflow is controlled so that more air enters the center of the column, causing the tablets to rise in the centre. (shown in fig.7)
4. **Miscellaneous Process**

Freund hi-coater.

Other side-vented coating pans, which are very similar to the Glatt Coater and the Accela cota, are manufactured by Dumoulin in France and by Freund in Japan who manufacture the Hi-Coater. (Shown in fig.8)

COATING TECHNIQUES

Generally three methods are used for tablet coating

- A. Coating
- B. Film coating
- C. Enteric coating

A. 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

Tablet gets its final color.

Polishing

Powdered wax (beeswax or carnauba) is applied to provide a desired luster. ^[10]

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 (shown in fig.9). 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 [11].

ENTERIC COATING

An enteric coating is a barrier that controls the location of oral medication in the digestive system where it is absorbed. The word “enteric” indicates small intestine; therefore enteric coatings prevent release of medication before it reaches the small intestine.

ADVANTAGES OF TABLET COATING

- 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.
- 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.
- They are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
- Cost is lowest of all oral dosage form.
- Lighter and compact.
- Easiest and cheapest to package and strip.
- Easy to swallowing with least tendency for hang-up.

DISADVANTAGES OF TABLET COATING

- Disadvantages of sugar coating such as relatively high cost long coating time and high bulk have led to the use of other coating materials.
- However the process of coating is tedious and time-consuming and it requires the expertise of highly skilled technician. The process is tedious and time-consuming and it requires the expertise of highly skilled technician.
- Difficult to swallow in case of children and unconscious patients.
- Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.

DIFFERENT TABLET COATING TECHNOLOGIES

1. Aqueous Film Coating Technology
2. Non-destructive quantification of pharmaceutical table coatings using terahertz pulsed imaging and optical coherence tomography

3. Orally disintegrating tablet (ODT) technology
4. Analysis of the tablet coating process: Impact of operation conditions on film quality
5. Novel Approach of Bilayer tablet technology
6. Trends in Pharmaceutical Taste Masking Technologies: A Patent Review
7. Butterfly Coating Technology
8. Electrostatic coating Technology
9. Magnetically assisted impaction coating (MAIC)

AQUEOUS FILM COATING TECHNOLOGY

History of aqueous film coating

Initially, aqueous processes were met with skepticism because of the longer process time and the inferior appearance of the coated product. A few desired release functions were obtainable only with organic solvent-soluble films. However, the development and introduction of latex and pseudo latex materials as well as improvements in equipment design have broadened the spectrum of aqueous coating.

Aqueous film coating

Aqueous film coating is applied as a thin polymeric film to the surface of a tablet. Film Coating can protect the tablet from light, temperature and moisture; mask undesirable taste or odor; improve the appearance; provide tablet identity; facilitate swallowing and control or modify the release of the drug. Aqueous coating of oral solid dosage forms has rapidly replaced solvent based coating for safety, environmental and economic reasons.

Mechanisms of Film Formation

Aqueous film coating applications are either solutions or dispersions, depending on the water solubility of the film former polymers. Film formation from the polymer solution occurs through a series of phases. When the polymer solution is applied to the surface of the tablet, cohesion forces form a bond between the coating polymer molecules.

Process Parameters

Spray rate

The spray rate is significant parameter since it impacts the moisture content of the formed coating. Subsequently the quality and uniformity of the film. A low coating liquid spray rate causes incomplete coalescence of polymer due to insufficient wetting, which could effect in brittle films. A high coating liquid spray rate may result in over wetting of the tablet surface and subsequent problems such as picking and sticking. If the spray rate is high and the tablet surface temperature is low, films are not formed during the spraying but the post drying phase, and rapid drying often produces cracks in the films.

Atomizing air pressure

In general, increasing the spraying air pressure decreases the surface roughness of coated tablets and produces denser and thinner films. If spraying air pressure is excessive, the spray loss is great, the formed droplets are very fine and could spray-dry before reaching the tablet bed, resulting in droplet spreading and coalescence.

Inlet air temperature

The inlet air temperature affects the drying efficiency (i.e. water evaporation) of the coating pan and the uniformity of coatings.^[12] High inlet air temperature increases the drying efficiency of the aqueous film coating process and a decrease in the water penetration into the tablet core, decreases the core tablet porosity, tensile strength and residual moisture content of coated tablets [12,13].

Rotating speed of pan

It is well documented that increasing the rotating speed of the pan improves the mixing of tablets [14-17]. The pan speed affects the time the tablets spend on the spraying zone and, subsequently, the homogeneous distribution of the coating solution on the surface of each tablet throughout the batch. Increasing the pan speed decreases the thickness variation and increase the uniformity of coatings [14,17,18]. Too much rotating speed of the pan will cause the tablet to undergo unnecessary attrition and breakage.

Current trend of aqueous film coating in pharmaceutical oral solid dosage forms

Aqueous coating technology remains the main option for film coating of oral solid dosage forms. This is irrespective of the purpose of the film-coating applications, i.e. for conventional and modified-release film coatings. The main reasons for its continued popularity are the environmental limitations of organic solvents used, recent advances in the formulation of aqueous film-coating materials, as well as major improvements made in the coating machines and their ancillaries. Aqueous coating systems are widely used for conventional film-coating systems (immediate release), enteric film-coating systems (delayed release), and barrier membrane controlled release film-coating systems [19].

Non-Destructive Qualification Of Pharmaceutical Tablet Coatings Using Terahertz Pulsed Imaging And Optical Coherence Tomography

Optical coherence tomography (OCT) and terahertz pulsed imaging (TPI) are two powerful techniques allowing high quality cross-sectional images from within scattering media to be obtained non-destructively. In this paper, we report experimental results of using OCT and TPI for quantitatively characterizing pharmaceutical tablet coatings in the thickness range of 10–140 μm . We found that the spectral OCT system developed in-house has an axial resolution of 0.9 μm , and is capable of quantifying very thin coatings in the range of 10–60 μm . The upper limit of 60 μm within the tablet coating and core is owed to the strong scattering of OCT light, which has relatively short wavelengths in the range of 0.5–1.0 μm . On the other hand, TPI utilizes terahertz radiation that has substantially long wavelengths in the range of hundreds of microns, and thus is less prone to the scattering problem. Consequently TPI has been demonstrated to be able to quantify thicker coatings in the range of 40–140 μm and beyond. Hence, study concluded that OCT and TPI are two complementary analytical techniques for non-destructive and quantitative characterization of pharmaceutical tablet coatings.

THE NEW GENERATION OF ORALLY DISINTEGRATING TABLET (ODT) TECHNOLOGES

The new generation of orally disintegrating tablet (ODT) technologies is no longer limited by dosage strength, bitter active pharmaceutical ingredients (APIs), and narrow therapeutic applications. Today's emerging technologies can produce robust, versatile tablets with exceptional taste masking and controlled release, broadening the applications of this dosage form. Pleasant-tasting tablets that "melt in your mouth" may lead to improved safety and compliance. ODTs also benefit pharmaceutical companies because they extend product lifecycle and patent protection.

ODTs have become one of the fastest-growing segments of the oral drug delivery industry, and their product pipeline is rapidly expanding [20]. Studies have shown that most consumers prefer ODTs to conventional tablets [21].

Desirable characteristics of ODT technologies

The major objective of ODT technologies is to develop patient-friendly tablets that dissolve rapidly in the mouth with a pleasant taste and mouth-feel. When the tablets are placed in the mouth, the API-containing particles should be undetectable so that patients do not experience a gritty feeling. In addition, there is often a requirement to achieve a specific plasma concentration of the therapeutic agent in order to establish bio-equivalence to a reference drug product.

A new generation of ODTs

Among the new generation of ODTs available today, is one that can be combined with a proprietary process to improve taste masking, allow a modified-release profile, and enhance bio-availability. As a result, formulators can taste-mask even extremely poor-tasting drugs, use high doses of API, and expand the range of therapeutic applications. This ODT comprises rapidly dispersing micro granules, a direct-compression blend, and an external tablet lubrication method. The result is an ODT with excellent physical robustness, mouth-feel, and disintegration properties. The tablets dissolve in 15 to 30 seconds (depending on dosage strength) and produce a smooth, pleasant-tasting mixture of API granules and carrier that is easy to swallow.

Taste masking

Combining micro-encapsulation with ODT technology effectively taste-masks bitter APIs and can be applied to soluble and poorly soluble substances, as well as to high-dose products. One technology is based on coacervation, a coating technique that encapsulates individual drug particles completely and provides superior taste masking.

This coacervation technique has taste-masked a wide range of extremely poor-tasting drugs, including zolpidem (for insomnia), sumatriptan (for migraines), ranitidine (for gastro-esophageal reflux disorder), and cetirizine (for allergic rhinitis).

Bio-equivalence

One of the biggest challenges for an ODT that uses taste-masking polymers is achieving bio equivalence with the conventional form (reference product). The polymers can impede API release in the gastrointestinal (GI) tract, delaying the onset of action. Using a micro encapsulation technique restricts dissolution of the API in the mouth, but allows rapid dissolution in the GI tract, thus overcoming the bio-equivalence obstacle. See Figure 14. An example of the new generation of ODT technology using modified coatings to achieve bio equivalence-is my company's formulation of cetirizine, the API in Pfizer's Zyrtec. Cetirizine is extremely bitter and cannot be formulated into an ODT with standard taste-masking approaches. Cetirizine is also chemically incompatible with many common excipients, and standard tablet making approaches could yield an unstable drug product.

Controlled release

Combining ODTs with specialized functional polymers and coating processes can lead to ODTs with sustained-, modified-, and customized-release profiles. It is even possible to combine release profiles in a single dose. Typical of these approaches are micro-encapsulation and multi-particulate coating technologies, which allow formulators to create modified-release polymer layers around API particles. These particles are flexible enough for compression without breakage or loss of the modified-release properties and small enough to provide good mouth feel. Adjusting the coating parameters (thickness, composition, porosity, pH modifying agents, and number of layers) changes the desired plasma profile. Technologies provides sustained release by layering active drugs onto a neutral core (bead), followed by one or more rate-con-trolling, functional membranes, is rapidly available when the API reaches the acidic environment of the stomach. Furthermore, the polymeric coating materials are compatible with cetirizine, providing a stabilization barrier between the API and excipients.

Manufacturing ODTs

Three technologies are commonly used to produce ODTs with appropriate tablet porosity: direct compression, freeze drying, and molding. Direct compression is the preferred method because it uses conventional equipment and materials, minimizing manufacturing costs. Compressed tablets are less fragile than the freeze-dried form. Another ODT technology is freeze-drying (lyophilization), which sublimates water from the product after freezing. While freeze-dried wafers, such as the Cardinal Health's Zydys technology, offer slightly faster dissolution than other ODTs, the tablets are light and fragile, and thus require a special blister pack. Freeze-drying is also limited by the time and handling required for processing, the amount of materials that can be processed in each batch, and the high cost of the equipment and processing [22].

Promising future

With the rapid acceptance of ODTs by patients and pharmaceutical companies, the market for this dosage form is promising and the product pipeline continues to grow rapidly [20]. ODTs offer convenience and potentially improved patient compliance. They also offer life-cycle management opportunities for pharmaceutical marketers. In combination with other technologies, such as modified release and micro-encapsulation, ODTs will continue to provide enhanced therapeutic and commercial benefits. Future challenges for many ODT manufacturers include reducing costs by finding ways to manufacture with conventional equipment, using versatile packaging and improving mechanical strength and taste-masking capabilities.

ANALYSIS OF THE TABLET COATING PROCESS: IMPACT OF OPERATION CONDITIONS ON FILM QUALITY

Spray coating is frequently used in the pharmaceutical industry to control the release of the active pharmaceutical ingredient of a tablet or to mask its taste. The uniformity of the coating is of significant importance, as the coating usually has critical functional properties. However, coating uniformity is difficult to predict without significant.

Spray system

A modern coating system is conceptually (shown in Fig.10), where the coating suspension is sprayed on top of a moving bed of the solid dosage form. The spray guns are usually mounted on an arm inside the pan and are directed towards the tablet bed. As the bed is moving, a tablet spends a fraction of a second in the spraying zone. (shown in fig.10) The wet surface of the Tablet needs to be dried to avoid sticking of the tablet to neighboring tablets, leading to manufacturing problems such as picking. However, too fast drying is counter-productive as well, as other problems may occur, such as the formation of a heterogeneous. The drying air is directed towards the surface of the tablet bed to achieve good heat and mass transfer.

In summary, the major objectives of this work are as follows

1. Model the spray, deposition on the tablet, the coating process, as well as the evaporation of the spray and the wall film in order to estimate the effects of the drying gas.
2. Numerically analyze the impact and deposition of droplets on particles with different shape,
3. Study the production and evolution of the liquid film on the surface of the tablets and

NOVEL APPROACH OF BILAYER TABLET TECHNOLOGY

Over the past 30 years as the expense and complications involved in marketing new drug entities have increased, with concomitant recognition of the therapeutic advantages of controlled drug delivery, greater attention has been focused on development of sustained or controlled release drug delivery systems. Bilayer tablet is new era for the successful development of controlled release formulation along with various features to provide a way of successful drug delivery system. So use of bilayer tablet is a very different aspect for anti-inflammatory and analgesic. Bi-layer tablet is suitable for sequential release of two drugs in combination, separate two incompatible substances and also for sustained release tablet in which one layer is immediate release as initial dose and second layer is maintenance dose [23,24].

Need OF Bilayer Tablets [24, 25, 26]

1. For the administration of fixed dose combinations of different APIs [13], prolong the drug product life cycle, buccal delivery systems [15] fabricate novel drug delivery systems such as chewing device and floating tablets for gastro-retentive drug delivery.
2. Controlling the delivery rate of either single or two different active pharmaceutical ingredient(s)
3. To modify the total surface area available for API layer either by sandwiching with one or two inactive layers in order to achieve swellable/erodible barriers for modified release.

ADVANTAGES OF THE BI-LAYER TABLET DOSAGE FORM

1. Bi-Layer execution with optional single-layer conversion kit. .
2. Cost is lower compared to all other oral dosage form.
3. Greatest chemical and microbial stability over all oral dosage form.
4. Objectionable odor and bitter taste can be masked by coating technique.

DISADVANTAGES OF BI-LAYER TABLET DOSAGE FORM

1. Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.
2. Bitter testing drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating.

TRENDS IN PHARMACEUTICAL TASTE MASKING TECHNOLOGES : A PATENT REVIEW

According to the year 2003 survey of pediatricians by the American Association of Pediatrics, unpleasant taste was the biggest barrier for completing treatment in pediatrics. The field of taste masking of active pharmaceutical ingredients (API) has been continuously evolving with varied technologies and new excipients. The article reviews the trends in taste masking technologies by studying the current state of the art patent database for the span of year 1997 to 2007.

TASTE MASKING TECHNOLOGIES

Coating

Coating is one of the most efficient and commonly used taste masking technologies. Here, it is classified based on the type of coating material, coating solvent system, and the number of coating layers. Hydrophobic polymers, lipids, sweeteners and hydrophilic polymers can be used as coating materials, either alone or in combination, as a single or multi-layer coat, to achieve the taste masking by aqueous or organic based coating process.

Granulation

Mixture of bitter medicaments and sweeteners, hydrophobic polymers, lipids or waxes can be processed by dry, wet and melt granulation techniques to prepare taste masked oral solid or liquid dosage forms. Bertelsen *et al.* (2006) described the melt granulation to achieve the taste masking of calcium-containing compounds like calcium carbonate. Melt granulation of a calcium-containing compound with a sugar alcohol as a binding agent resulted in granules with an acceptable taste and mouth feel Granulation is a less expensive, rapid operation and an easily scalable taste masking technology.

Sweeteners

Water soluble organic acids promote salivation to facilitate the formation of a viscous and mould able particle paste, which can ease the swallowing of coated particles. They can be mixed with bitter taste medicaments to improve the taste of the core material which is prepared for further coating or may be added to the coating liquid. Sweeteners have been commonly used for the taste masking of pharmaceuticals. Artificial sweeteners such as sucralose, aspartame and saccharin have been used in combination with sugar alcohols such as lactitol, maltitol and sorbitol to decrease the after-taste perception of artificial sweeteners.

Microencapsulation

Microencapsulation is a valuable technique applicable to protect materials from volatilizing, oxidation as well as to mask their unpleasant taste Microencapsulation processes are commonly based on the principle of solvent extraction or evaporation. However, modifications of other techniques such as phase separation (coacervation) and spray-drying are also utilized for microencapsulation Spray congealing is another method of microencapsulation.

Taste Suppressants and Potentiators

Most of the Linguagen's bitter blockers (e.g. adenosine monophosphate) compete with bitter substances to bind with the G-protein coupled (GPCR) receptor sites. In general the hydrophobic nature of these bitter substances contributes greatly to their binding and inter-action with the receptor sites. Lipoproteins are universal bitter taste blockers.

Ion Exchange Resins

Ion exchange resins are high molecular weight polymers with cationic and anionic functional groups. Resins form insoluble resinates through weak ionic bonding with oppositely charged drugs and maintain low concentration of the free drug in a suspension.

Viscosity Enhancers

Suspending coated particles or microcapsules may not be efficient enough to achieve taste masking of highly bitter medicaments in liquid oral suspensions. Usage of viscosity enhancers in these cases would retard the migration of dissolved medicament from the surface of the solid particle to the suspending medium. Additionally, they can also decrease the contact between the bitter medicament and the taste receptors, thus improving the overall taste masking efficiency.

Complex Formation

Complexing agents have been utilized to mask the objectionable taste of drugs. The mechanism of taste masking by complex formation has two theoretical possibilities. Either the cyclodextrins wraps the bad tasting molecule to inhibit its interaction with the taste buds, or it interacts with the gate-keeper proteins of the taste buds. Cyclodextrin was used to achieve taste masking of levosulpiride by complex formation. Sweeteners such as acesulfame can form complex with medicaments to achieve taste masking.

pH Modifiers

pH Modifying agents are capable of generating a specific pH microenvironment in aqueous media that can facilitate *in situ* precipitation of the bitter drug substance in saliva thereby reducing the overall taste sensation for liquid dosage forms like suspension.

Adsorbates

Adsorbates are commonly used with other taste masking technologies. The drug may be adsorbed or/and entrapped in the matrix of the porous component, which may result in a delayed release of the bitter active during the transit through the oral cavity thereby achieving taste masking.

THE BUTTERFLY COATING PAN TECHNOLOGY

These pans have capacities ranging from 15 litres up to 1200 litres and are manufactured in Germany by Huttlin. (Shown in fig.11) Originally developed for sugar coating, they are claimed to be suitable for all current types of film coatings, and in particular for larger tablets. The Butterfly pan has a special pan cross-section with inward-sloping sides. The cross section of the pan containing the product area is shaped like a trapezium. In contrast to all other sugarcoating pans this pan has its largest breadth at the biggest cross-section and its smallest breadth at the smallest cross section. Therefore, even with maximum load the height through which the product falls is relatively small. Intensive product movement is achieved which provides optimal mixing. In the interior of the pan there are no blades or other baffles to mechanically stress the product. The loading and evacuation of the tablets (or pellets) is performed tangentially from the sides of the pan through segments in the wall. This is a unique system which provides a very efficient handling process [27].

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 (shown in fig.12).

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 [28, 29, 30, 31].

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 (Shown in fig.13) Particles, (d) magnetic–host–host particle interaction, (e) Magnetic–host–wall interaction and (f) coated products. [32] Although there is some heat generated on a micro scale due to the collisions of particles during MAIC, it is negligible [32].

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.

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 color

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 [33,34].

Tablet evaluation

1. 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.
2. Adhesion test with tensile strength testers are used to measure the force needed to peel the film from the tablet surface.
3. 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.
4. Exposure to elevated humidity and measurement of tablet weight gain provide relative Information on the protection provided by the film [35].

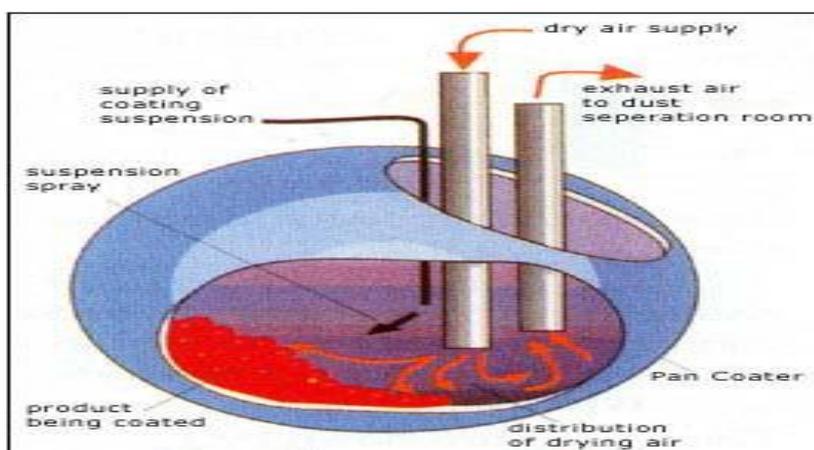


Figure 1: Pan Coating Process with dry air

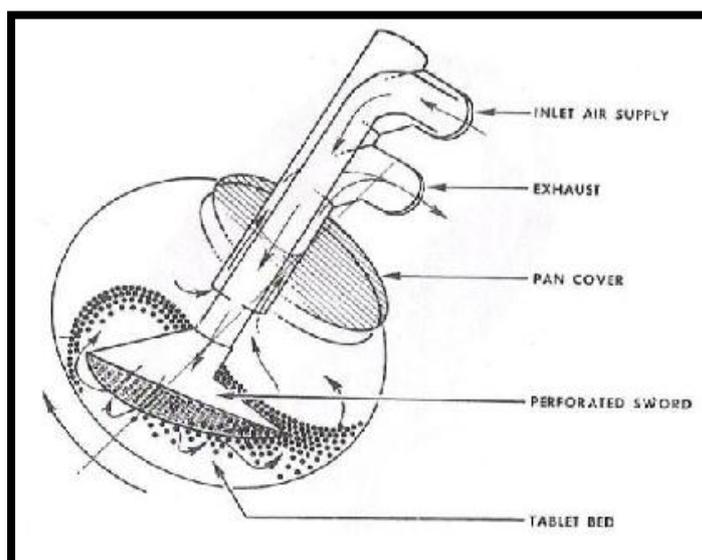


Figure 2: Immersion-sword system

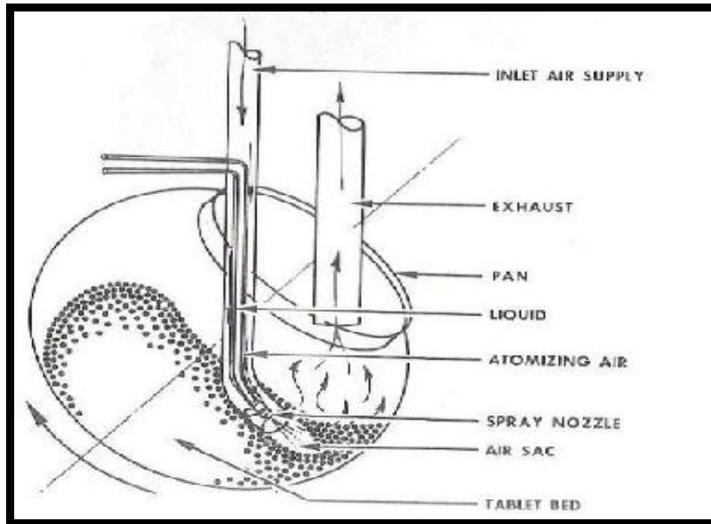


Figure 3: Immersion tube system

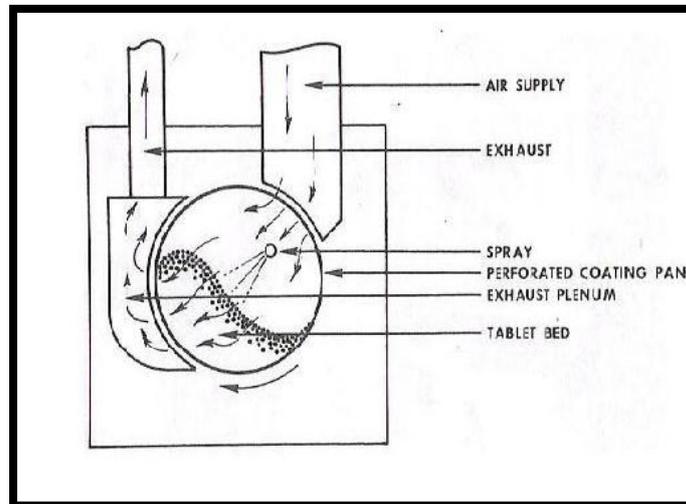


Figure 4: Accela coat system

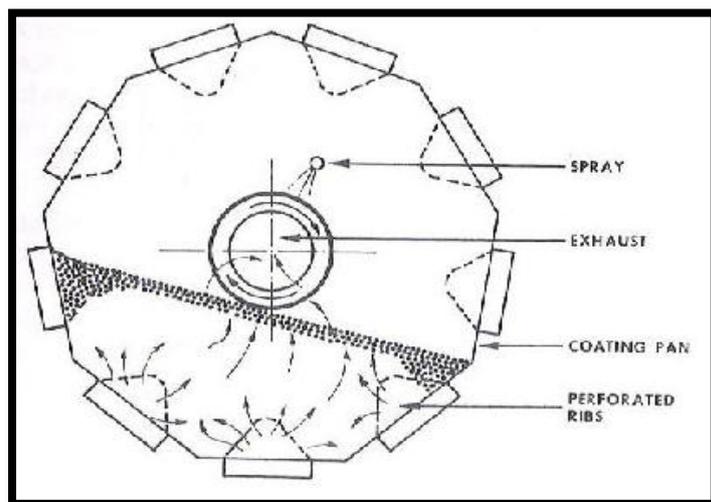


Figure 5: Driacoater

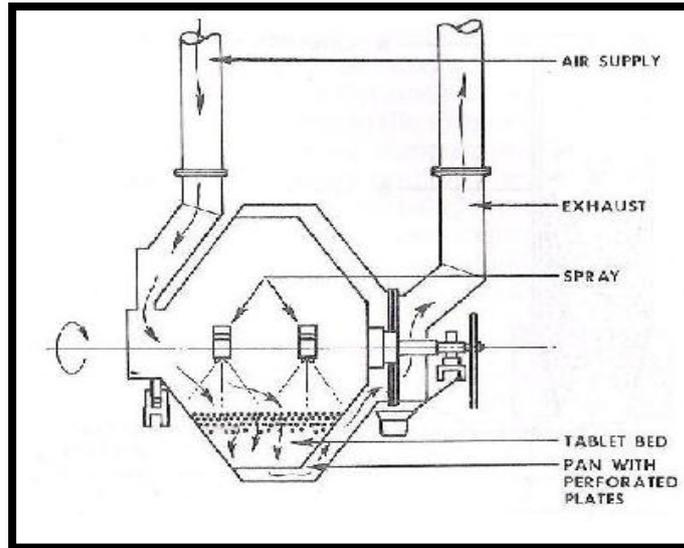


Figure 6: Hi-coater system

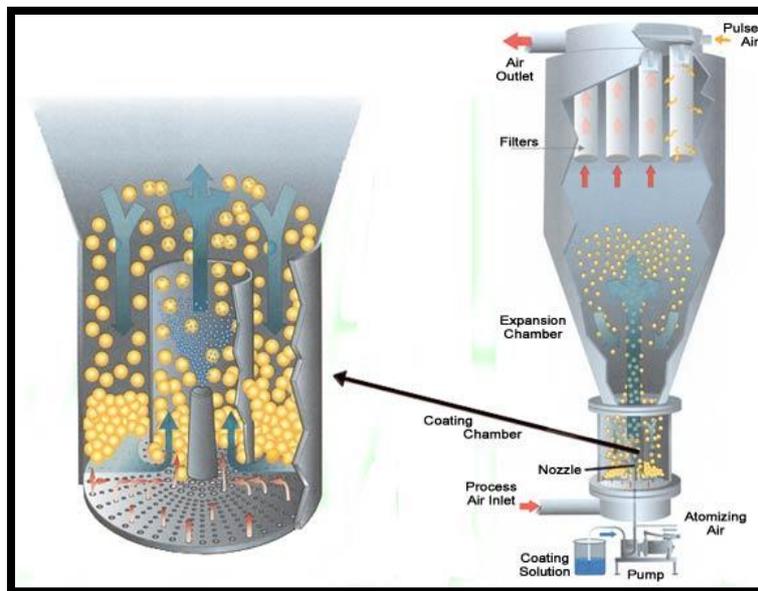


Figure 7: Fluidized bed coater

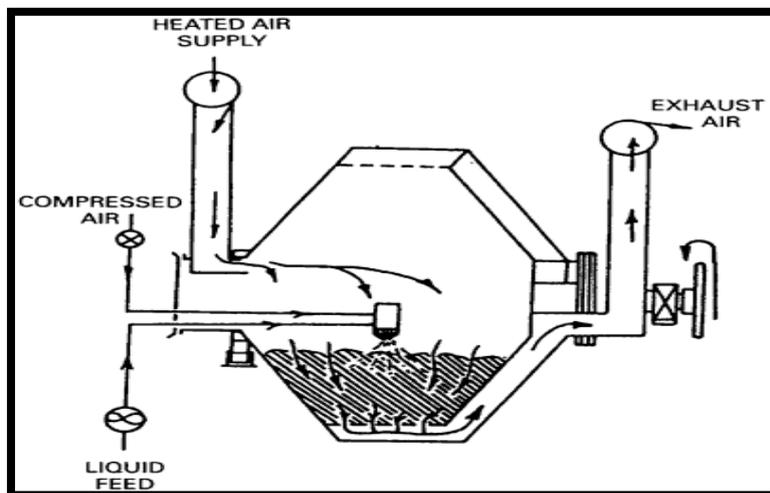


Figure 8: Freund Hi-Coater.

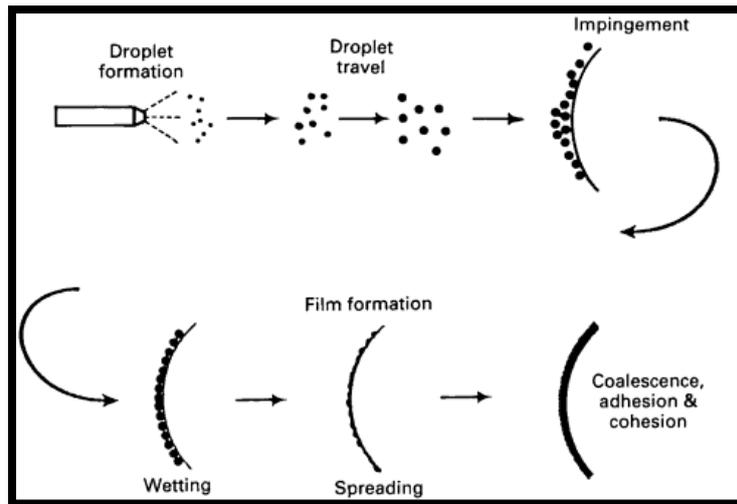


Figure 9: Stages in spray film coating.

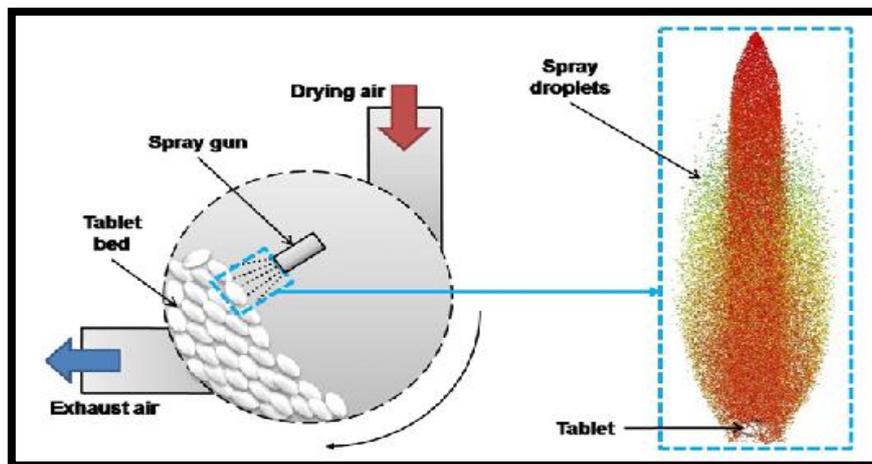


Figure 10: Schematic of a modern pan coater (side-vented) and domain for the spray

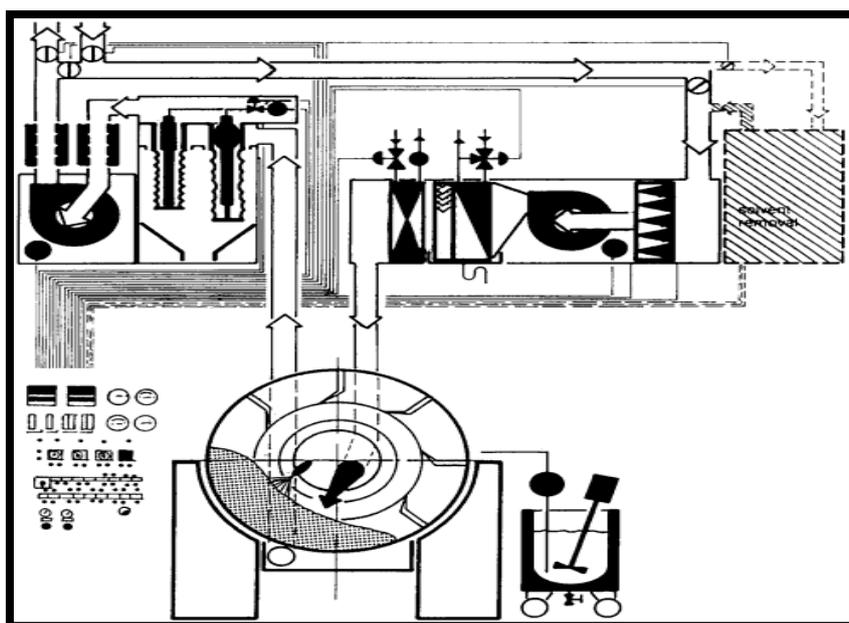


Figure 11: The Butterfly coating pan

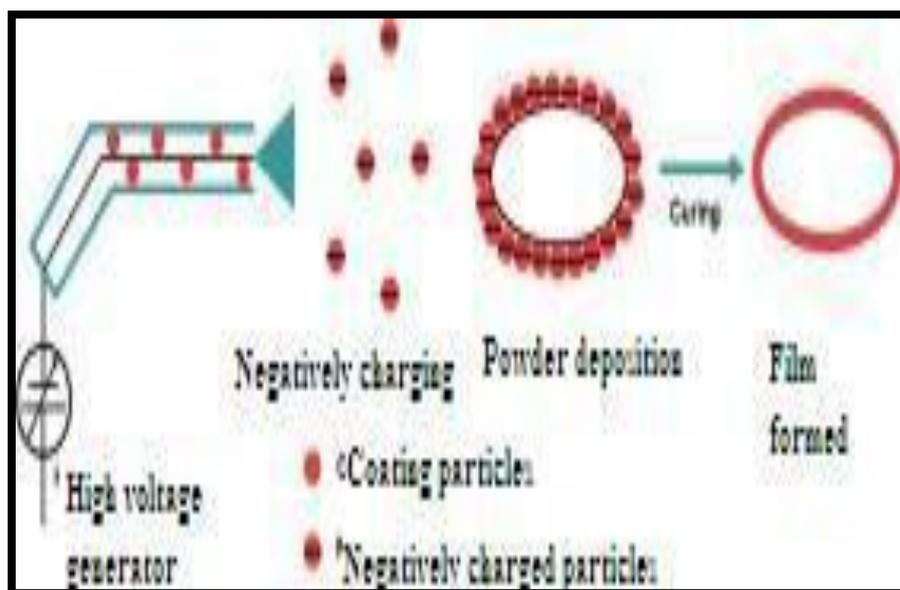


Figure 12: Mechanism of electrostatic coating.

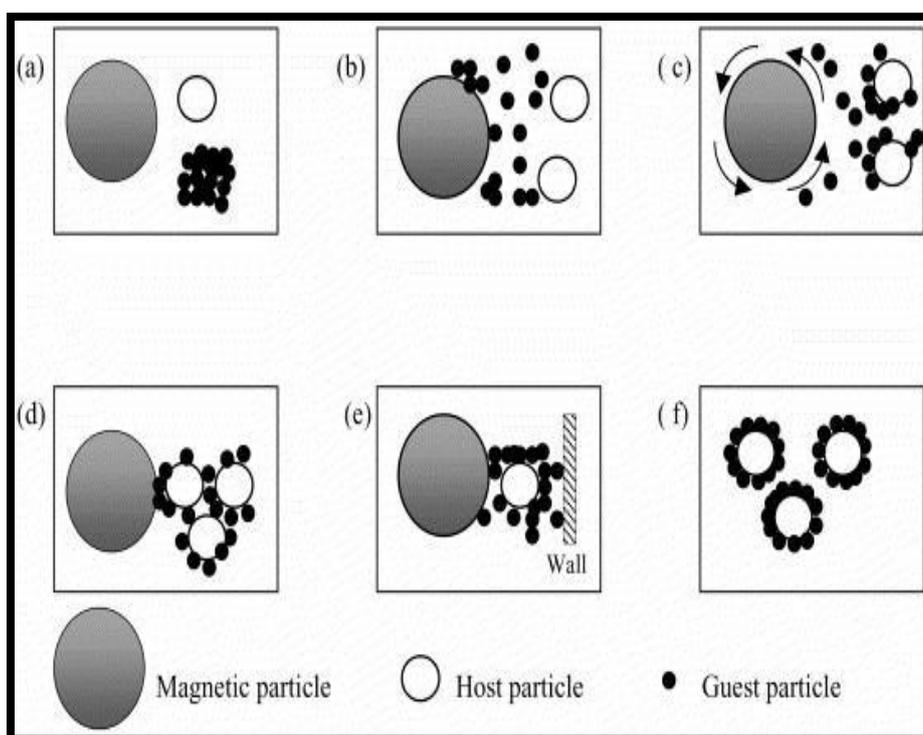


Figure 13: Mechanism of coating in the MAIC process: (a) excitation of magnetic particle, (b) de-agglomeration of guest particles, (c) shearing and spreading of guest particles on the surface of the host (d) Attachment with guest particles (e) Covering of particles on host particle (f) Total covering of guest particles on guest particle.

REFERENCES

- [1] Kamble N. et al. International Journal of Applied Biology and Pharmaceutical Technology, 2011: 214-218.
- [2] Lachman Leon et al, The Theory and Practice of Industrial Pharmacy, Second edition, Fourth Indian Reprint, Published by Varghese Publishing house, Bombay. 1991: 346-372.
- [3] Cole G. Pharmaceutical Coating Technology Taylor Francis, Ltd. 3rd edition 1998;1-5
- [4] Porter C. Coating of Pharmaceutical Solid-dosage forms, Pharm. Tech. Second edition 1980; 4(3), 66.

- [5] Lieberman H. and Lachman L. *Pharmaceutical Dosage Forms: Tablets*. Vol. I to III, Marcel Dekker Inc., N.Y, Second edition. 85-143.
- [6] Remington J. *The Science and Practice of Pharmacy; Nineteenth Edition: Volume II*, 1615-1641
- [7] Aulton M. *Pharmaceutics: The Science of Dosage Form Design*. International Student Edition, 304-321, 347-668.
- [8] Behzadi S. *Innovations in coating technology, recent patents on drug delivery & formulations*, 2008; 209-230
- [9] Gupta A. et al, *Tablet coating techniques: concepts and recent trends*,
[10] www.irjponline.com.
- [11] Kamble N. et al. *International Journal of Applied Biology and Pharmaceutical Technology*. 2011: 214-218.
- [12] Dr. Colin H. *Importance of surface Finish in the Design of Stainless Steel*, *Stainless Steel Industry*, 15 August 2006.
- [13] Twitchell A, Hogan J and Aulton M. *STP Pharm Sci* 1995; 190-195.
- [14] Poukavoos N. and Peck G. *Drug Dev Ind Pharm* 1994; 20:1535-1554.
- [15] Jantzen G. and Robinson J. *Sustained and controlled-release drug delivery systems*. In: Banker GS, Rhodes CT, editors. *Modern pharmaceutics*. 4th Edition, New York: Marcel Dekker; 2002, 501–28.
- [16] Zeitler J. Gladden L. *European J Pharm Biopharm* 2008; 71:2–22,
[17] Cahyadi C, Karande A, Chan L, Heng P. *Int J Pharm* 2010; 398, 39–49.
- [18] Perez-Ramos JD, Findlay WP, Peck G, Morris KR. *AAPS Pharm Sci Tech*, 2005; 6(1):E127–36.
- [19] Obara S. and Ginity J. *Int J Pharm* 1995; 126: 1-1
- [20] Graham C, Taylor and Francis, *Pharmaceutical Coating Technology*, 2002, Pg. No. 65-66
- [21] *Technology Catalysts International*, "Oral Fast-Dissolving Drug Delivery: Technologies, Market Analysis, & Business Opportunities." August 2003.
- [22] Hamilton E. and Lutz E, "Orally Disintegrating Tablets," *Drug Delivery Technology*, January 2005.
- [23] Dobbetti L, "Fast-Melting Tablets: Developments and Technologies," *Pharmaceutical Technology, Drug Delivery* 2001, 44-50.
- [24] Shiyani B, Gattani S, Surana S. *AAPS Pharm Sci Tech* 2008; 9(3):818-27.
- [25] Singh P, Kumar S. *J Drug Del Therap* 2011;1(1): 32-35
- [26] Kulkarni A, Bhatia M. *Iran J Pharm Res* 2009; 8: 15–25
- [27] Nirmal J, Saisivam S, Peddanna C, Muralidharan S, Nagarajan M, et al. *Chem Pharm Bull* 2008; 56: 1455–1458, 26-102-1 PB
- [28] Graham C, Taylor and Francis, *Pharmaceutical Coating Technology*, edited by Publication, 2002, Pg. No. 227-229
- [29] Qiao M. et al. *European J Pharm Biopharm* 2010: 304-310
- [30] Pawar A. et al, *International Journal of Chem. Tech Research*. 2010: 733-737.
- [31] Mazumder M, Sims R, Biris A. *Chem Eng Sci* 2006; 61: 2192-2211.
- [32] 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.
- [33] Ramlakhan M, Chang Yu Wu, Watano S, Dave R, Pfeffer R. *Powder Technol* 2000; 112(1-2): 137-148.
- [34] <http://vikramthermoblogspot.in/2011/06picking-and-sticking.html>
- [35] <http://www.pharmainfo.net/rajapicota1023/blog/problems-associated-tablet-manufacturing>
- [36] Rowe R. *Acta Pharm Technol* 1983; 29(3): 205-207.