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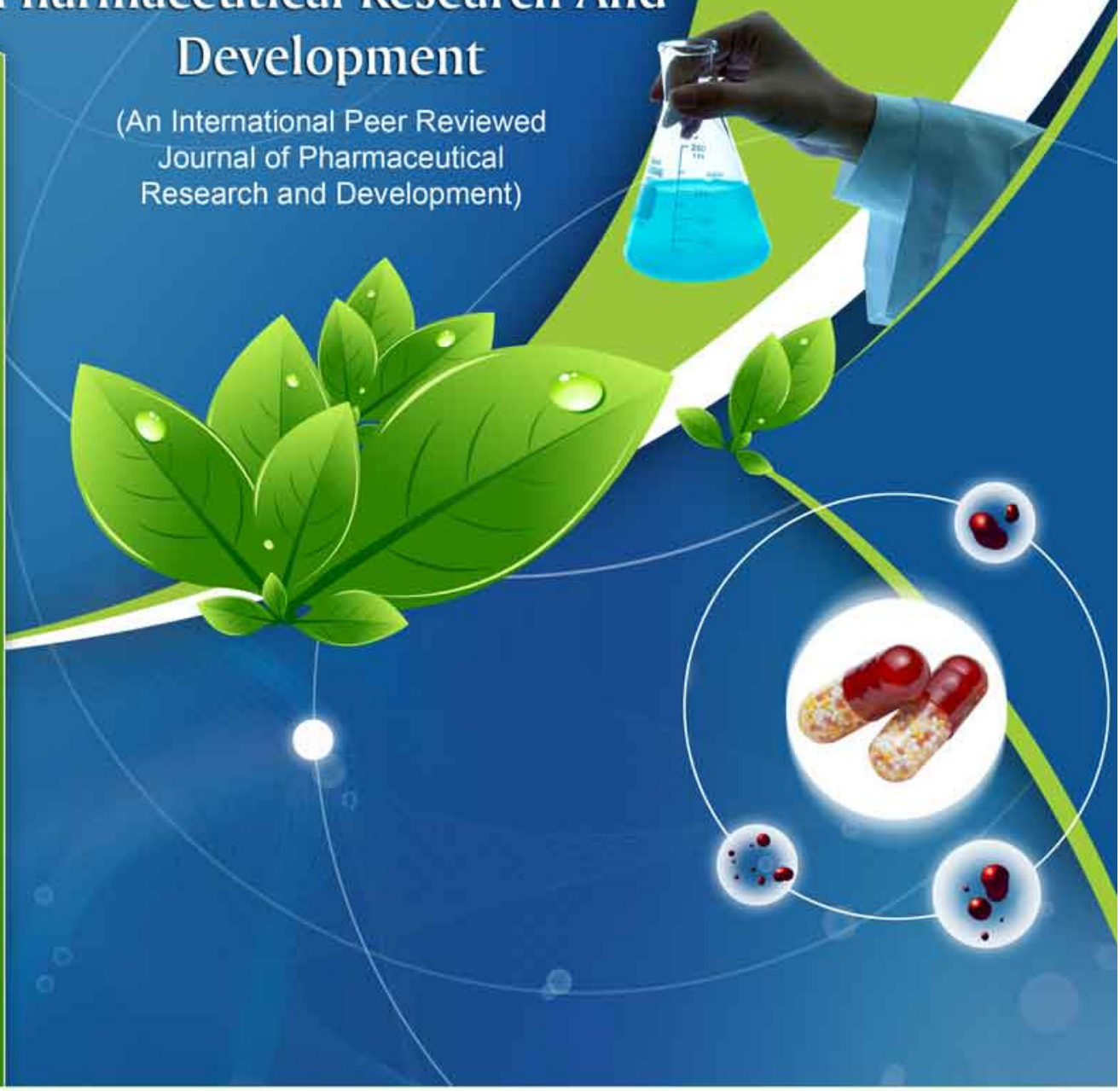

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Review Article

A REVIEW: NOVEL SOLVENTLESS COATING TECHNIQUES FOR TABLET DOSAGE FORM.

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ABSTRACT

Tablet coating is perhaps one of the oldest pharmaceutical processes still in existence. Earlier, Sugar coating was adopted for pharmaceutical purpose from confectionary industry. But as it was tedious process and required skilled manipulation, film coating was started to be preferred over sugar coating. Development of film coating was mainly based on solutions of different polymers in various organic solvents. All these solvents are not environment friendly and toxic in nature. Till date the problems like material cost, toxic effects due to coating or pollution etc were of less concern. In today's competitive business environment, any cost saved will improve the success of any product. Therefore, industries are left with no other choice but to eliminate the use of organic solvents and to start using the solvent less system for tablet coating. The main focus of this review is, to study various methods of solvent less tablet coating techniques.

KEYWORDS*: Solvent less, compression coating, Photo curable, Impaction, Supercritical*

INTRODUCTION

Tablet coating

The application of coatings to the surface of pharmaceutical solid-dosage forms especially tablets has been practiced for over 150 years. Although such a process is often applied to a dosage form that is functionally completes and thus may cause us to reflect on the need for incurring the additional expense. It is evident that the continued use of coating processes in pharmaceutical production remains very popular**.** [1] Such popularity relates to the many benefits obtained when a dosage form is coated, which include:

- Improved aesthetic qualities of the product.
- Masking of unpleasant taste and odour.
- Enabling the product to be more easily swallowed by the patient.
- Facilitating handling particularly in high-speed filling packaging lines.
- Improving product stability.
- Modifying drug-release characteristics.

Sugar coating is done for a variety of reasons on tablets and pills, which include, giving a pleasant taste or prevention of bitter taste, to improve stability and to modify the release of the drug.

Film-coating is a thin, polymer-based coat applied to a capsule or tablet in which cellulose derivatives such as hydroxyl propyl methylcellulose or other cellulose polymers are used. Most film coatings are applied as aqueous or organic based polymer solutions. Both organic and aqueous film coating have their own disadvantages.

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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. But there are several disadvantages associated with its use. [2, 3]

- They are flammable and toxic
- Their vapour causes hazards to coating equipment operator
- High cost of solvent
- Solvent residue in formulation.
- Strict environmental regulations by US Food and Drug Administration (USFDA), Environmental Protection Agency (EPA) and Occupational Safety and Health Administration (OSHA). [4, 5]

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. However, water-based coatings also suffered from following problems.

- Heat and water involved in coating process can degrade the drug.
- Validation of coating dispersion for controlling microbial presence.
- Solvent removal process is time consuming and extremely energy consumptive. [6]

In order to overcome above mentioned limitations of liquid coating technology, new efforts have been made in recent years to develop a solvent less coating technology. Solvent less coating technologies can overcome many of the disadvantages associated with the use of solvents (e.g., solvent exposure, solvent disposal and residual solvent in product) in pharmaceutical coating. Solvent less processing reduces the overall cost by eliminating the tedious and expensive processes of solvent disposal/treatment. In addition, it can significantly reduce the processing time because there is no drying/evaporation step. [6]

SOLVENTLESS COATING TECHNIQUE

Non-solvent coating is introduced as alternative coating technique to overcome these disadvantages. Non-solvent coatings have been categorized as [7, 8]

- Compression/Press coating
- Dry powder coating
- Heat dry coating
- Supercritical fluid spray coating
- Magnetically assisted impaction coating
- Photo curable coating

Compression/press coating

Compression coating, or press-coating, has been introduced during the period 1950 1960 to formulate incompatible drugs. This coating became interesting in the last two decades owing to the advantages over liquid coating, since the process does not need the use of solvents, requires a relatively short manufacturing process and allows greater weight gain to the core tablet. Nowadays, pharmaceutical aspects of compression-coated tablets in dosage form development are:

- To protect hygroscopic, light-sensitive, oxygen labile or acid-labile drugs;
- To separate incompatible drugs from each other and achieve sustained release;
- To modify drug release pattern (delayed, pulsatile and programmable release for different drugs in one tablet). [9]

However, some drawbacks of compression-coating technique are: the requirement of reliable and reproducible central positioning of the core tablet within compression-coated tablet, the need of a multiple-step process or a special tableting machine. Recently, the common manufacturing problems for compression-coated tablets, such as central positioning of the core in the compression-coated tablets and absence of core in coat, have been overcome by applying a novel one-step dry coated tablet (OSDRC) method. [10]

Powder/Dry Coating:

Thin film powder coating, also referred to as a “dry painting” process, eliminates volatile organic compounds (VOCs), hazardous air pollutants (HAPS) and solvents, and produces superior surface finish. There are four basic powder coating application processes: electrostatic spraying fluidized bed, electrostatic fluidized bed and flame spray. [11]

The principle of the powder coating technology involves spraying of a mixture of finely ground particles and polymer onto a substrate surface without using any solvent, and then heating the substrate in a curing oven until the powder mixture is fused into a coating film. [12] Different powder coating processes have been developed for the metal and wood finishing industry during the last 30 years: electrostatic spraying, fluidized bed coating, electrostatic fluidized bed coating and flame spray, among which electrostatic spraying is the most common process used for application of powder coatings in metal finishing.

Compared with the traditional liquid coating technology, the powder coating technology is highly valued for energy and time savings, nearly 100% utilization of the coating materials, long shelf life, environmental friendliness, safety and therefore low overall operation costs. [13, 14] Furthermore, the coating process is simplified because important parameters of liquid coating processes have not to be considered, e.g., evaporation parameters. Applications of the powder coating technology have been successful in metal and wood finishing, which has enlightened a new application in the pharmaceutical industry to coat solid dosage forms.

- **Electrostatic spraying powder dry coating**

The basic principle of electrostatic spraying concerns propulsion of the dry powder by compressed air through a spray gun, by which it becomes electrically charged and then moves and adheres to the earthed substrate surface. [15] A successful electrostatic spraying should satisfy several requirements: a powder charging and dispensing unit, an earthed conductive substrate and powder particles able to be charged. There are two types of spraying units, generally in the form of powder charging guns, according to the charging mechanisms: corona charging and tribo charging. Corona charging guns are characterized by electrical breakdown and thereafter ionization of air by imposing a high voltage on a sharp pointed needle-like electrode (i.e., charging pin) at the outlet of the gun, and the powder particles picking up the negative ions on their way from the gun to the substrate, while tribo charging guns make use of the principle of frictional charging associated with the dielectric properties of solid materials and therefore no free ions and electrical field will be present between the spray gun and the grounded substrate. An electrical charge is applied to the dry powder particles while the component to be painted is electrically grounded. The charged powder and grounded workpiece create an electrostatic field that pulls the paint particles to the workpiece. The coating deposited on the workpiece retains its charge, which holds the powder to the workpiece. The coated workpiece is placed in a curing oven, where the paint particles are melted onto the surface and the charge is dissipated. [16, 17]

- **Fluidized bed powder dry coating**

Powder particles are kept in suspension by an air stream. A preheated workpiece is placed in the fluidized bed where the powder particles coming in contact with the workpiece melt and adhere to its surface. Coating thickness is dependent on the temperature and heat capacity of the workpiece and its residence time in the bed. Post heating is generally not required when applying thermoplastic powder coatings. However, post heating is required to completely cure thermoset powder coatings. [18, 19]

- **Plasticized powder dry coating**

In plasticizer-dry-coating technology, powdered materials are sprayed onto dosage surface simultaneously with the plasticizer spraying from separate spraying nozzle. The sprayed liquid plasticizer would wet the powder particles and the dosage surface, promoting the adhesion of particles to dosage surfaces. The coated dosages are then cured for a predetermined time above the *T*g of the polymer, forming a continuous film. [20, 21] The adhesion of particles to dosage surface is mainly the result of the said wetting of particles and dosage surfaces by plasticizers, and the film formation is the combined response of improved viscous flow and particle deformation resulted from plasticizer

and heat. [20] In addition, capillary forces exerted by liquid plasticizer prior to its uptake into the polymer particles may also contribute to the particle deformation in the interstitial capillary system between particles and thus to the film formation. In their plasticizer-dry coating process, spraying a small amount of water or hydroxypropyl methylcellulose (HPMC) solution to their HPMCAS-coated spheres could obviously improve the film quality; Pearnchob and Bodmeier also suggested that moisture would significantly accelerate the film formation and optimize the film smoothness and integrity of ethylcellulose-coated pellets during the heat curing phase. [22] These phenomena are similar to those observations for film formation of aqueous dispersions. [23] For these cases, water or water in the polymer solution plays a role of coalescing solvent or plasticizer promoting the inter diffusion of polymer chain, and the evaporation of water may also provide a driving force to fuse the polymeric particles based on the film formation mechanism proposed for aqueous latex systems. [24, 25]

It has some benefits over ordinary coating techniques

Powder coating eliminates the need for expensive and often toxic solvents, the control equipment, employee exposure, disposal requirements liabilities associated with liquid coating (wet solvent) use.

Because the powder is dry when sprayed, any overspray can be readily retrieved and recycled, regardless of the complexity of the system, resulting in shorter cleanup times. In all cases, the dry powder is separated from the air stream by various vacuum and filtering methods and returned to a feed hopper for reuse. Powder efficiency (powder particles reaching the intended surface) approaches 100 %. [26, 27]

Heat Dry Coating:

This method is named as heat dry coating by Y. Luo et al. as only heat was used as a binding force to realize the dry coating of tablets. [28] In this coating technology Eudragit E-PO (a polymer based on dimethylaminoethyl methacrylate and methacrylates) particles were continuously spread onto the tablet contained in a lab scale spheronizer by way of motorized single screw powder feeder, with an infrared lamp positioned on the top of the spheronizer as a heating source, without using any solvent and plasticizer. [29]

The heat dry coating process occurs in the three stages:

- Pre-heating: In this stage the uncoated tablets are heated to the predetermined temperature.
- Powdering: In this stage the powder is transferred into the coating equipment and distributed onto the cores.
- Curing: Here polymeric particles adhere to the surface of the substrate to form a polymeric film coating.

The polymer having lower glass transition temperature (Tg) generally requires no plasticizers. The polymer having higher Tg pre-plasticization was employed by blending polymers with plasticizers using the hot melt extrusion method. [30] Generally, film formation of the plasticized polymer particles is expected to occur already at temperatures below the pure polymer's glass transition temperature. This is caused by the plasticizer reducing the polymer's Tg which results in elevated mobility and softness of the polymer molecules. Thus, the film formation temperature should be lower in comparison to the glass transition temperature of the pure polymer. [31] The advantage of heat dry coating includes abandoning plasticizers for lower Tg film forming polymers, or avoiding high concentrations of plasticizers because of pre-plasticization. However, it is a challenge for heat dry coating to get a smooth, uniform and thick coating only by the help of heat based adhesion. [32]

Supercritical fluid coating/microencapsulation

The "supercritical fluid spray coating" process consists of dissolving the coating material or drug in supercritical carbon dioxide, and gradually reducing the solvent power of carbon dioxide to enable the coating material

to precipitate onto drug particles dispersed in the medium. Although this process is technically a solvent-based coating process, the use of carbon dioxide as the supercritical fluid avoids some of the challenges associated with traditional solvent-based processes. In the absence of co-solvents, the coating materials used in supercritical fluid coating are limited mainly to lipids (fats and waxes). [33, 36] Microencapsulation using supercritical fluid technology combines a liquid-like density and solvating power with gas-like transport properties (like viscosity, diffusivity). Carbon dioxide is the most widely used supercritical fluid because of its relatively low critical temperature (31°C) and pressure (74 bar). The use of supercritical fluid technology, especially CO_2 for encapsulation purposes is mainly due to the mild processing condition, allowing microencapsulation of sensitive ingredients for cosmetics, pharmaceuticals. Supercritical fluids are especially suitable for particle formation, as they display a large change in density near the critical point which enables their solvating power to be carefully controlled by small changes in temperature or pressure. Ideally, deposition should occur as a defect-free film or coating. [37, 38]

Magnetically assisted impaction coating (MAIC)

This method is studied by Michelle R. by coating the fine silica particles onto the surface of larger cornstarch and cellulose particles. [39] 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. 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 better candidates for such applications. The magnetically assisted impaction coating devices can coat soft organic host and guest particles without causing major changes in the material shape and size. The rise in temperature is negligible; this is an added advantage when dealing with temperature sensitive powders such as pharmaceuticals. [40] Apparatus for MAIC consists of processing vessel surrounded by the series of electromagnets connected to the alternating current. The host and guest materials are placed in the vessel along with the measured mass of the magnetic particles. When a magnetic field is present, the magnetic particles are agitated and move furiously inside the vessel, resembling a fluidized bed system. These agitated magnetic particles then impart energy to the host and guest particles, causing collisions and allowing coating to be achieved by means of impaction of the guest particles onto the host particles. 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. [41] However, the effect of the translational speed is also significant as it allows for the impaction of one particle onto another, promoting coating.

Mechanism of coating in the MAIC process is

(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) Formation of coated products.

The system parameters to be considered are magnetic particle size, mass ratio of magnetic particles to powder host and guest particles, guest particle size. The operating parameters are processing time, current or voltage, frequency. [41]

Photocurable coating

Unlike other solventless coating techniques that rely on changes in the physical state of the coating material to obtain a coating, photocuring is a chemical approach proposed to rapidly coat tablets at or below room temperature with an extremely rapid rate. [42, 43] Photocuring systems generally consist of 4 major components:

- UV/visible light source,

- Specially functionalized liquid pre-polymers or monomers
- An initiator.
- Pore forming agents

It is common to define photocuring as a process of rapid conversion of specially formulated (usually liquid) solventless compositions into solid films by irradiation with ultraviolet or visible light. [44, 45] A large proportion of the curing reactions described above are carried out with light in the ultraviolet region. [46] This is due to the fact that ultraviolet light is more energetic and, therefore, more efficient in rupturing chemical bonds. On the other hand, the use of visible light has many attractions, such as safety and ease of handling. So, lately, curing with visible light is receiving attention as well. [47] Photocuring can be divided into two groups, those that cure by free-radical mechanism and those that cure by an ionic mechanism viz. cationic (mostly), anionic mechanism. There are also some compositions that cure simultaneously by both mechanisms.

CONCLUSION

All the coating methods reported above are solventless coating methods which eliminates or minimizes the various drawbacks associated with the conventional solvent based coating methods. The conventional pan coater, fluidized bed coater and spray dryer can be used with slight modification for most of the solventless coating methods. But electrostatics coating magnetically assisted coating and supercritical fluid coating needs specialized designed apparatus. Plasticizer dry coating and heat dry coating have to overcome difficulties in obtaining uniform and smooth coating before their commercial application, rest of other methods are able to produce coat with sufficient thickness and smoothness. Electrostatic coating is capable of applying different coating colors on the same formulation. Though these methods have greater advantage over conventional coating methods, before commercialization of these methods further work should be focused on scale-up tests, functional detection of coated solid dosage forms such as drug release profile and clinical tests to make them more useful, economical and safe.

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