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### An update on electrostatic powder coating for pharmaceuticals

### Qingliang Yang<sup>a,c</sup>, Yingliang Ma<sup>a,b</sup>, Jesse Zhu<sup>a,c,\*</sup>, Kwok Chow<sup>b</sup>, Kaiqi Shi<sup>c</sup>

<sup>a</sup> Particle Technology Research Centre, Department of Chemical and Biochemical Engineering, University of Western Ontario, London, Ontario N6A 5B9, Canada

<sup>b</sup> Powder Pharma Coatings, Mississauga, Ontario L5R 2Y9, Canada

<sup>c</sup> Ningbo Weston Powder Pharma Coatings Co. Ltd., Ningbo, Zhejiang 315 042, China

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#### ABSTRACT

Derived from dry powder coating of metals, electrostatic powder coating for pharmaceuticals is a technology for coating drug solid dosage forms. In this technology, coating powders, containing coating polymers, pigments, and other excipients, are directly sprayed onto the surface of the solid dosage forms through an electrostatic gun without using any organic solvent or water. The deposited coating powders are further cured to form a coating film. Electrostatic powder coating technology has many advantages compared to other pharmaceutical coating methods. It can eliminate the limitations caused by the organic solvent in solvent coating such as environmental issues and health problems. And electrostatic powder coating technology also surpasses aqueous coating due to its shorter processing time and less energy consumption, leading to a lower overall cost. Furthermore, the utilization of electrical attraction can promote the movement of coating powders towards the substrate, leading to an enhanced coating powder adhesion and coating efficiency, which make it more promising compared to other dry coating technologies. The objective of this review is to summarize the coating principles, apparatus, and formulations of different electrostatic powder coating technologies, giving their advantages and limitations and also analyzing the future application in the industry for each technology.

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#### Introduction

In the pharmaceutical industry, solid dosage forms, including tablets and pellets, are always coated to enhance drug's physi-

E-mail address: jzhu@uwo.ca (J. Zhu).

cal and chemical properties, to achieve odor/taste masking and also to alter drug release profiles including immediate release, sustained/controlled release, and delayed release (Siepmann, Bodmeier, & McGinity, 2013). The aim of immediate release coating is to obtain odor/taste masking and protect the drug from moisture and/or light. Sustained/controlled release coating allows drug releasing slowly within a desirable time period, which can decrease dosing frequency and enhance patient adherence, reducing or eliminating side effect associated with high peak plasma concentration (Liu et al., 2012). Enteric coating could achieve drug delayed release,

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<sup>\*</sup> Corresponding author at: Particle Technology Research Centre, Department of Chemical and Biochemical Engineering, University of Western Ontario, London, Ontario NGA 5B9, Canada.

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protecting the drug from gastric acid and enzymes for the first two hours at low pH (typically seen in stomach) and releasing drug immediately after exposed to the higher pH of the small intestines (Liu et al., 2012).

Nowadays liquid coating methods, including solvent coating and aqueous coating, are widely used in the pharmaceutical industry to obtain the coating film for those solid dosage forms. In the solvent coating process, coating polymers and other excipients are dissolved into an organic solvent to form a coating solution, which is sprayed onto the surface of the solid dosage forms to form a coating film by evaporating the organic solvent (Liu et al., 2012). The film formation from organic solvent coating occurs by evaporating organic solvent during the drying process and bringing into contact of individual polymer molecules (Pearnchob & Bodmeier, 2003; Wesseling & Bodmeier, 1999). As a result, the film formation from solvent coating is guite uniform. However, it can cause many problems due to the presence of organic solvent such as toxicity and environmental concerns. Besides, the concentration of the coating solution cannot be very high owing to the viscosity limit, leading to a long processing time to achieve high coating thickness.

As a result of toxicity and environmental concerns, aqueous coating started to dominate in 1990s and remains the preferred approach in the present pharmaceutical industry. For water soluble polymers, the coating process and film formation mechanism are the same as organic solvent coating. For water-insoluble polymers, the coating process and film formation are different. Coating polymers and additives are firstly ground into fine powders. After mixed together, those fine powders are dispersed into water to form a coating suspension. This suspension is then sprayed onto the surface of the solid dosage forms, followed by an evaporating by a flow of hot air and curing step to allow the polymer particles coalescing into a homogeneous film. Plasticizers are often added into the coating formulation to reduce the glass transition temperature  $(T_{\sigma})$ of the coating polymer (Pearnchob & Bodmeier, 2003). Although there is no toxicity and environmental related problems for aqueous coating, it still possesses many limitations. First, water is more difficult to be evaporated compared to organic solvent, leading to a much longer processing time and much higher energy consumption. Also hot air and its handling are necessary to evaporate water in the coating process, which could further increase the overall cost. In addition, aqueous coating is not appropriate for the moisture sensitive drugs.

In order to overcome the disadvantages caused by organic solvent and water in the coating process, dry coating technologies have been developed and reported (Bose & Bogner, 2007; Luo, Zhu, Ma, & Zhang, 2008; Sauer, Cerea, DiNunzio, & McGinity, 2013). These technologies include compression coating (Rujivipat & Bodmeier, 2012), photocuring coating (Kutal, Grutsch, & Yang, 1991), supercritical coating (Ni, Xu, Xu, Wang, & Yin, 2011; Yue et al., 2004), hot-melt coating (Achanta, Adusumilli, James, & Rhodes, 1997; Dreu, Lustrik, Perpar, Zun, & Srcic, 2012; Hampel, Buck, Peglow, & Tsotsas, 2013), and dry powder coating (Cerea, Zheng, Young, & McGinity, 2004; Kablitz, Harder, & Urbanetz, 2006; Kablitz, Kappl, & Urbanetz, 2008; Kablitz & Urbanetz, 2007; Obara, Maruyama, Nishiyama, & Kokubo, 1999; Pearnchob & Bodmeier, 2003). Although those dry coating technologies could minimize some limitations of liquid coating caused by organic solvent and water, the requirements for specific coating conditions and suitable coating materials make it hard to apply them in the pharmaceutical industry.

In the compression coating process (Rujivipat & Bodmeier, 2012), mixture of core formulation is first compressed into an inner layer core and then coating materials is compressed around the core to form an outer layer film. The main problem for the compression coating is that the coating thickness is not uniform owing to the reproducibility issues of placement of the core in the center.

Photocuring coating (Kutal et al., 1991) involves a free-radical polymerization reaction of photocurable materials to form a crosslinked network. This coating process can be performed rapidly at room temperature or below and it is the only reported chemical approach so far to form the coating film. But this coating method is not suitable for the photosensitive drugs. Also its use is limited by the specific photocurable materials and coating equipment. Supercritical fluid coating (Ni et al., 2011; Tsutsumi, Nakamoto, Mineo, & Yoshida, 1995; Yue et al., 2004) can be used to coat small particles uniformly by encapsulating each core with coating materials under a supercritical condition. However, the application of this coating method is limited due to the poor solubility of most coating materials in supercritical fluid and also the requirement of the core to be insoluble. For the hot-melt coating (Achanta et al., 1997; Chen, Shi, Liu, & Tang, 2010; Jannin & Cuppok, 2013; Sinchaipanid, Junyaprasert, & Mitrevej, 2004), coating materials is applied in their molten state. The coating process includes several steps. First, the coating equipment is warmed, and then substrate is preheated. Coating materials is melted and sprayed onto the surface of the substrate, followed by the cooling step to allow the film formation. This coating method is only suitable for the drug with stable properties at or below the congealing point of the coating materials.

While for the dry powder coating technologies (Kablitz et al., 2006, 2008; Kablitz & Urbanetz, 2007; Pearnchob & Bodmeier, 2003), liquid plasticizers have to be sprayed onto the surface of the solid dosage forms to reduce minimum film formation temperature and surplus plasticizer can possibly lead to very soft or sticky film, so that careful balance needs to be reached between the plasticizer concentration for a sufficient coat thickness and that for a flexible and dry coat. And also the coating powder feeding cannot be well controlled and it is difficult to get a smooth and thickness-uniform coating film.

Compared to those dry coating technologies, electrostatic powder coating has gained more attention owing to its distinct advantages, such as short coating process, highly valued for energy savings, and significantly reduction of overall operation cost. And most importantly, electrostatic powder coating not only could enhance the coating powder adhesion so as to significantly increase the coating efficiency, but also could control the coating powder feeding and achieve more uniform coating film both on coating thickness and surface morphology. Recently many electrostatic powder coating technologies have been developed for pharmaceutical dosage forms, including coating apparatus and coating formulations. Some of these technologies are very close to be applied in the industry due to those mentioned advantages. A summary of such works can bring lots of benefits to this area.

The aim of this review is to give an introduction and discussion on the basic principles, coating equipment, coating process and future development of electrostatic powder coating technologies for pharmaceuticals.

#### Electrostatic powder coating for pharmaceuticals

#### Principles

The concept of electrostatic powder coating came out in the 1950s in USA, and now it is widely used in the industry coatings, furniture and construction industries. In the electrostatic powder coating process (Fig. 1), dry powders are charged by an electrostatic spray gun and then move and adhere to the grounded substrate surface without using any solvent or water. And then the grounded substrate with deposited coating powder is put in an oven and cured for a certain period of time under high temperature to allow film formation.

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