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Review

Composite particles based on particle engineering for direct compaction

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ABSTRACT

Direct compaction (DC) is the preferred method for tablet production. However, only a minority of the active pharmaceutical ingredients (APIs) can be truly manufactured into tablets by DC so far due to that most of APIs lack sufficient functional properties required for DC. Particle engineering with co-processing provides a promising way to obtain various composite API and/or excipient particles with markedly improved functional properties, which makes successful tableting of them by DC possible. This review, as an informative update and supplement, covers the improvement of functional properties of composite API and/or excipient particles via co-processing based on recent developments and researches in the area of particle engineering for DC. The improved functionality of co-processed particles and corresponding mechanisms were summarized and discussed from the perspective of structure characteristics (Crystal level and Particle level) as the properties of particles are markedly affected by their structure.
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1. Introduction

Originated in the mid-19th century, the tablet continues to be the dosage form of choice and constitutes about half of solid dosage forms in contemporary use (Li et al., 2016; Rasenack and Muller, 2002; Adeoye and Alebiowu, 2014; Gohel and Jogani, 2005). There are three basic methods for tablet production, i.e., *wet granulation*, *dry granulation*, and *direct compaction* (DC). In spite of numerous improvements in granulation techniques (Sahoo et al., 2016), DC has increased steadily over the years and is now the method of choice for tablet production because of its simple and continuous nature, time and cost effectiveness, and elimination of heat and moisture effects (Mangal et al., 2015; Garg et al., 2015; Eraga et al., 2015). However, it was reported that less than 20 percent of the active pharmaceutical ingredients (APIs) could be processed into tablets via DC since the majority of APIs lack good enough functional properties required for DC, such as flowability, tabletability, lubricating properties, and disintegration (Vanhoorne et al., 2014; Mirani et al., 2011). This has been improved by the development of co-processed drug and/or excipient particles with enhanced DC properties. Co-processed particles are specific combinations of two or more parent particles at a subparticle level designed to physically modify their properties in a way not achievable by simple physical mixing. Namely, developing co-processed particles is a research of particle engineering by which two or more different particles are physically combined into a single-bodied multifunctional particle with preferred properties, such as, most seen in the case of DC, better tabletability and flowability (Adeoye and Alebiowu, 2014; Saha and Shahiwala, 2009; Gonnissen et al., 2007; Adeagbo and Alebiowu, 2008).

Although particle engineering has become a widely used technique in the development of high functional particles, it is a young discipline that combines elements of microbiology, chemistry, formulation science, colloid and interface science, heat and mass transfer, solid state physics, aerosol and powder science, and nanotechnology (Vehring, 2008). By means of a profound understanding of the formation process and structure of co-processed particles, it provides the theoretical framework for a rational design of structured particles (Vehring, 2008). In general, particle engineering involves the manipulation at solid state levels such as particle, crystal, and bulk levels. The particle level involves individual particle properties (such as shape, size, surface area, and porosity) and the crystal level involves arrangement of individual molecules in the crystal particle (Mirani et al., 2011). Both of the particle and crystal levels can cause changes in the bulk level, which involves properties such as flowability, tabletability, etc (Mirani et al., 2011; York, 1992).

Particle properties can be divided into two groups: fundamental properties and functional properties. Functional properties, such as flowability, lubricant sensitivity, tabletability, dilution potential, and disintegration time, are determined by fundamental properties (Fig. 1), such as particle morphology, size, shape, surface area, porosity, and density (Rojas et al., 2012). These properties are interdependent. Particles with high functional properties can be achieved by modifying their fundamental properties (Rojas et al., 2012). Since fundamental properties of particles are mainly determined by particle structure, it is reasonable to believe that particle structure affects functional properties of particles significantly. It was reported that improved functional properties could be effectively achieved by particle surface modification, e.g., coating different types of guest particles on the surface of the host particles (Chen et al., 2010; Jallo et al., 2010; Han et al., 2011; Zhou et al., 2011b; Mullarney et al., 2011).

Literatures about co-processed DC particles mainly focus on the following two aspects: (i) the performance evaluation of commercially available co-processed particles (Arida and Al-Tabakha, 2008; Komersová et al., 2016; Haware et al., 2015) and (ii) the development of multifunctional excipients and co-processing methods (York, 1992; Zhao and Augsburger, 2005; Wetering et al., 2005; Coucke et al., 2009; Mohammed et al., 2008; Gonnissen et al., 2008; Garg et al., 2013). Several excellent reviews have been published in this field (Gohel and Jogani, 2005; Mirani et al., 2011; Rojas et al., 2012; Mangal et al., 2015). For example, Rojas et al. (2012) summarized and discussed the functionality

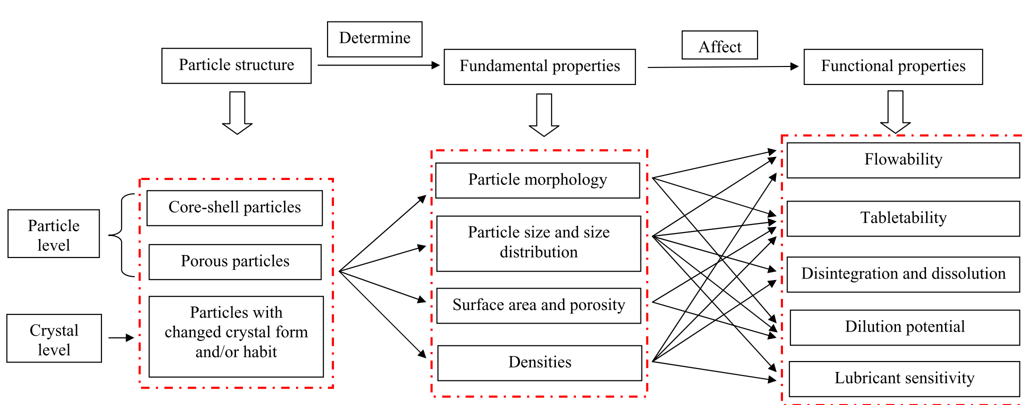

Fig. 1. Effects of particle structure on fundamental and functional properties of particles.

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