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Roller compaction: Effect of morphology and amorphous content of lactose powder on product quality

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ABSTRACT

The effect of morphology and amorphous content, of three types of lactose, on the properties of ribbon produced using roller compaction was investigated. The three types of lactose powders were; anhydrous SuperTab21AN, α-lactose monohydrate 200 M, and spray dried lactose SuperTab11SD. The morphology of the primary particles was identified using scanning electron microscopy (SEM) and the powder amorphous content was quantified using NIR technique. SEM images showed that 21AN and SD are agglomerated type of lactose whereas the 200 M is a non-agglomerated type. During ribbon production, an online thermal imaging technique was used to monitor the surface temperature of the ribbon. It was found that the morphology and the amorphous content of lactose powders have significant effects on the roller compaction behaviour and on ribbon properties. The agglomerated types of lactose produced ribbon with higher surface temperature and tensile strength, larger fragment size, lower porosity and lesser fines percentages than the non-agglomerated type of lactose. The lactose powder with the highest amorphous content showed to result in a better binding ability between the primary particles. This type of lactose produced ribbons with the highest temperature and tensile strength, and the lowest porosity and amount of fines in the product. It also produced ribbon with more smooth surfaces in comparison to the other two types of lactose. It was noticed that there is a relationship between the surface temperature of the ribbon during production and the tensile strength of the ribbon; the higher the temperature of the ribbon during production the higher the tensile strength of the ribbon.

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1. Introduction

Granulation is the size-enlargement process of particles to improve the flowability, compressibility and homogeneity of a downstream blend of materials. It is an essential process for converting fine powders into products with specific properties required in many industries such as food and pharmaceuticals. Granulation can be carried out with liquid (wet granulation) or without liquid (dry granulation).

The roller compactor is a common piece of equipment used for dry granulation. The equipment consists of two counter current rollers which come with different surfaces: smooth, fluted or knurled (Kleinebudde, 2004). These two rollers are used to apply high stress to the incoming powder to produce compacted material which is called a ribbon. The ribbon is then used to produce granules with desired size after passing through a milling step.

As a dry granulation process, there is no need for liquid binder during roller compaction in order to produce agglomerates. This is an advantage of dry granulation using a roller compactor over wet granulation as no drying stage is required, which means lower total cost. Another advantage of roller compaction is that it is a continuous process, which means it is easy to scale up and increase the overall process efficiency and reduce the operation cost (Bindhumadhavan et al., 2005; Kleinebudde, 2004). The main disadvantage of roller compaction is the large amount of fines that are produced during the process. The amount of fines is the amount of non-compacted powder which is produced during the compaction process, ribbon production, and after milling the ribbons to granules (Inghelbrecht et al., 1997; Miller, 1997).

Lactose is the most common powder used in the food and pharmaceutical industries (Listiohadi et al., 2008; Morita et al.,

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1984; Wang et al., 2015). It can be found in either a crystalline state, where the molecules are highly ordered, or in an amorphous state where the molecules are randomly arranged (Palzer, 2010). The presence of amorphous lactose in predominantly crystalline lactose has influences on powder compaction properties (Cal et al., 1996; Sebhatu and Alderborn, 1999; Vromans et al., 1987). The most common types of lactose available are anhydrous lactose, α-lactose monohydrate, and spray dried lactose. Lactose monohydrate is suitable for both wet and dry granulation purposes (DFE Pharma, Germany). Anhydrous lactose and spray dried lactose are the most common and recommended types of lactose for dry granulation and direct compaction (Morita et al., 1984; Sebhatu et al., 1997). The SD lactose is suitable for direct compaction of formulation with low dose, poorly flowing active ingredient, while 21AN lactose is intended to be used for dry granulation and direct compaction of moisture sensitive active ingredient (Huang et al., 2013). These types of lactose have different properties due to the different manufacturing processes. Anhydrous lactose is produced from the crystallization of a supersaturated solution of lactose above 93.5 °C by roller drying (DFE Pharma, Germany). The fast crystallization using roller dryer, results in the aggregation of lactose microcrystals (Vromans et al., 1985) and produces anhydrous lactose with compacted structure and a rough surface. The slow crystallization of a supersaturated lactose solution below 93.5 °C results in single crystals of α-lactose monohydrate. Crystals of α-lactose monohydrate are very hard and brittle with tomahawk-like shape. Spray dried lactose is produced by spray drying a suspension of α-lactose monohydrate in a solution of lactose. Because of fast drying process, the product consists of small particles of α-lactose monohydrate connected with amorphous lactose (DFE Pharma, Germany).

Several works have been done to study the behaviour of different types of powder during roller compaction using different process variables (Dumarey et al., 2011; Inghelbrecht and Remon, 1998a,b; Souihi et al., 2013). Compaction pressure is the most significant parameter that affects ribbons and granules properties during roller compaction (Gupta et al., 2005a,b; Inghelbrecht and Remon, 1998a,b; Osborne et al., 2013). Dumarey et al. (2011) studied the effect of using different grades of MCC, a plastically deform material, on ribbon, granule and tablet properties. They concluded that the MMC grades have significant effect on the product properties. One previous work to study the roller

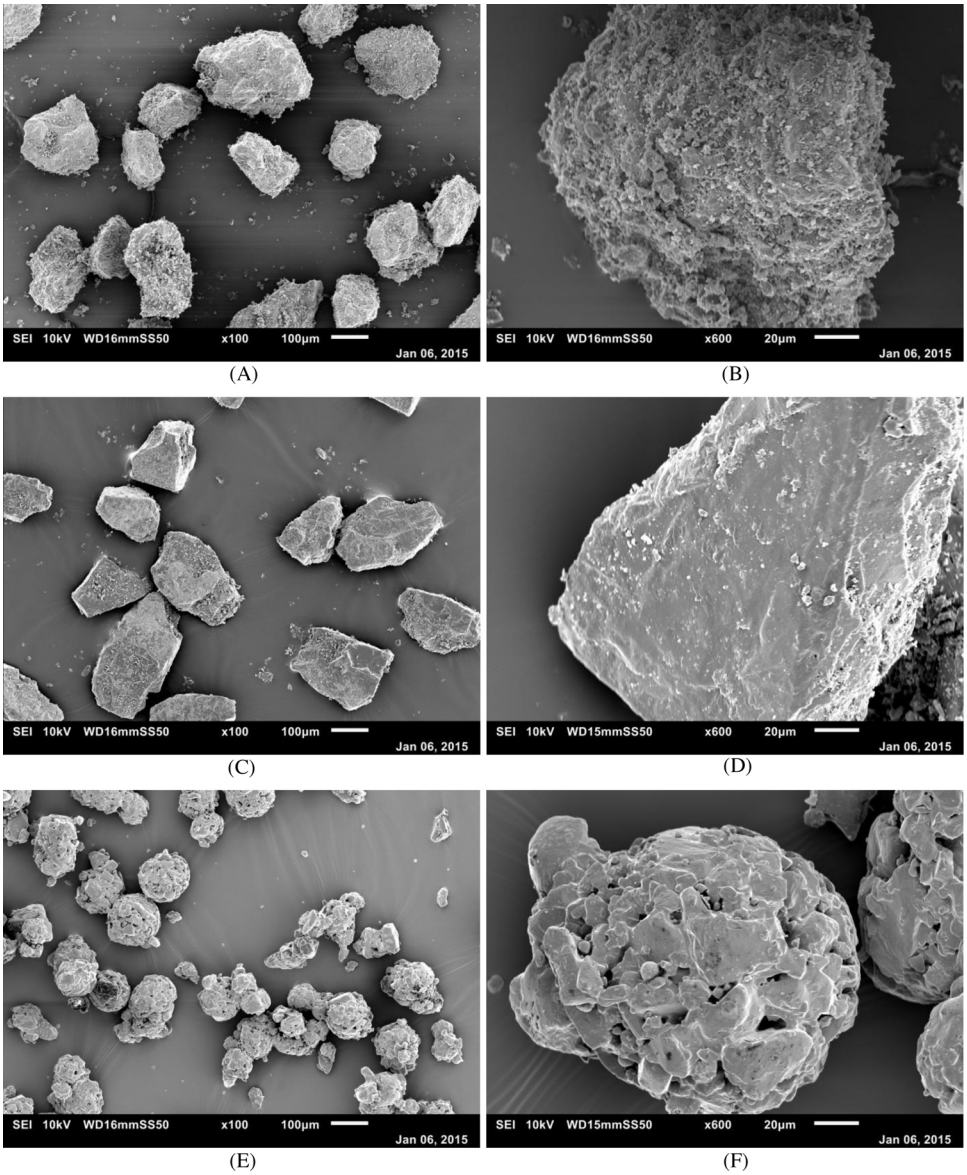

Fig. 1. Scanning electron microscope images of powders: 21AN (A, B), 200 M (C, D), SD (E, F) at 100× magnifications (A, C, E) and 600× (B, D, F).

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