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Research paper

Roller compaction: Effect of relative humidity of lactose powder

Chalak S. Omar [a], Ranjit M. Dhenge [a], Stefan Palzer [b], Michael J. Hounslow [a], Agba D. Salman [a,*]

[a] Department of Chemical and Biological Engineering, University of Sheffield, Mappin Street, Sheffield S1 3JD, UK
[b] Nestlé SA Headquarters, Avenue Nestlé 55, CH-1800 Vevey, Switzerland

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ABSTRACT

The effect of storage at different relative humidity conditions, for various types of lactose, on roller compaction behaviour was investigated. Three types of lactose were used in this study: anhydrous lactose (SuperTab21AN), spray dried lactose (SuperTab11SD) and α-lactose monohydrate 200M. These powders differ in their amorphous contents, due to different manufacturing processes. The powders were stored in a climatic chamber at different relative humidity values ranging from 10% to 80% RH. It was found that the roller compaction behaviour and ribbon properties were different for powders conditioned to different relative humidities. The amount of fines produced, which is undesirable in roller compaction, was found to be different at different relative humidity. The minimum amount of fines produced was found to be for powders conditioned at 20–40% RH. The maximum amount of fines was produced for powders conditioned at 80% RH. This was attributed to the decrease in powder flowability, as indicated by the flow function coefficient *ffc* and the angle of repose. Particle Image Velocimetry (PIV) was also applied to determine the velocity of primary particles during ribbon production, and it was found that the velocity of the powder during the roller compaction decreased with powders stored at high RH. This resulted in less powder being present in the compaction zone at the edges of the rollers, which resulted in ribbons with a smaller overall width. The relative humidity for the storage of powders has shown to have minimal effect on the ribbon tensile strength at low RH conditions (10–20%). The lowest tensile strength of ribbons produced from lactose 200M and SD was for powders conditioned at 80% RH, whereas, ribbons produced from lactose 21AN at the same condition of 80% RH showed the highest tensile strength. The storage RH range 20–40% was found to be an optimum condition for roll compacting three lactose powders, as it resulted in a minimum amount of fines in the product.

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1. Introduction

Granulation is a particle size-enlargement process carried out to improve flowability, compaction and homogeneity of a downstream blend of materials. This is an important process in many industries including the food, pharmaceuticals and chemical industries [1]. Granulation can either be performed as a dry or wet process. In wet granulation, a liquid is used as a binder to help the primary particles agglomerate, whereas during dry granulation, high stresses are applied to compress the primary particles into agglomerates.

Roller compaction is commonly used for dry granulation. The equipment consists of two counter rotating rollers of which the surface can be of many different forms [2]. The two rollers are used to apply a high stress to the incoming powder to produce compacts called ribbons. The ribbon is then milled in order to produce granules with the desired size. The absence of the liquid binder during dry granulation means there is no need for a drying step after granulation, which results in lowering the total cost of the process; this is an advantage of dry granulation. Another advantage of roller compaction is that it is a continuous process, which means it is relatively easy to scale up and increase the overall process efficiency, while reducing the operation cost [2,3]. The main disadvantage associated with roller compaction is the large amount of fines that are produced during the production of ribbons [4,5].

Lactose is an important material which is used in the food and pharmaceutical industries. It is a disaccharide that can exist in either a crystalline or an amorphous state [6]. The moisture content of various types of powders has been shown to affect the powder properties in many applications [7–13]. Previous work in the literature has been carried out to study the effect of powder moisture content on product properties during compression. Osborne et al. [7] showed the effect of moisture content of an amorphous food powder on ribbon properties during roller compaction. In

* Corresponding author. Tel.: +44 (0)114 222 7560.
E-mail addresses: c.omar@sheffield.ac.uk (C.S. Omar), a.d.salman@sheffield.ac.uk (A.D. Salman).

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their work, maltodextrin with different moisture contents was used to produce ribbons in the roller compactor. Ribbons were tested for their tensile strength and porosity and they were milled into fragments using a ball mill. It was found that ribbons produced from powder with high water content resulted in larger fragments when compared to the ribbon that was produced from powder at lower water content. This indicates that the ribbons were stronger when the initial powder had higher water content due to the high tensile strength and low porosity measured. This was attributed to a sintering mechanism which occurred during compaction of the powder with higher water content. Increasing the water content of amorphous powder decreases its glass transition temperature and its viscosity which results in the formation of solid bridges between the primary particles which in turn produces a stronger ribbon [7,9]. Powder moisture content was also found to affect the pressure (stress) applied by the rollers [10]. The study was carried out using microcrystalline cellulose (MCC) (Avicel PH-102) with different water content using a gravity feeding system. It was found that the maximum pressure (stress) applied by the rollers was the same for powders with a water content below 10%. However, the value of the maximum pressure increased sharply at a water content of 11.44% and then decreased with any further increase in water content. This was attributed to the increase in water content which resulted in a decrease in flowability and an increase in cohesivity of the powder, which increases the amount of powder present between the rollers, thereby increasing the pressure. The decrease in pressure upon a further increase in water content was attributed to the lubricating effect of the water. A similar result was shown by Gupta et al. [11] when MCC (Avicel PH-200) in a blend with 10% acetaminophen (APAP) was used to produce ribbons using a Chilsonator IR220 roller compactor. They found that ribbon tensile strength reaches an optimum value; the strength increased initially and then decreased with increasing powder moisture content. Ribbon density was also found to increase with increasing the powder water content. This behaviour was attributed to the presence of the APAP powder in the blend. An increase in moisture content resulted in facilitating the rearrangement of the APAP particles in the blend, which increases the formation of interparticulate bonds and leads to an increase in tensile strength and density of the ribbon.

However, some other studies showed contradicting results to the previous works mentioned, showing that compact tensile strength decreases with increasing moisture content for pure microcrystalline cellulose MCC (Avicel PH-200) [12]. In this study by Gupta et al., the ribbons were milled by passing them through a miller with an impeller, to produce granules. It was found that there was a decrease in the granule size with increasing powder water content prior to compaction.

One of the disadvantages of roller compaction is the amount of fines present while producing the ribbon. At present, limited work has been carried out in an effort to reduce the amount of fines in the roller compaction process [13]. Inghelbrecht and Remon [13] attempted to enhance the granule quality in the roller compactor by reducing the amount of fines during production. Different amounts of water were sprayed onto a mixture of Pharmatose 200M and Pharmacoat 606 (as a binder) to obtain powders with varying water contents. It was found that the amount of non-compacted powder decreased by increasing both the water content of the powder and the pressure during compaction. However, the powder water content above 11% was avoided, due to the formation of lumps and the sticking of powder on the roller during production.

The relative humidity of the environment can affect the powder moisture content during storage. The humidity of the environment changes significantly throughout the year in certain locations in the world, resulting in varying product qualities. Therefore, it is important to investigate the effect of varying the relative humidity during storing of powders, on powder properties and processing.

The aim of this work was to investigate the effect of storage at different relative humidity conditions for three types of lactose powders on roller compaction behaviour and on the properties of the ribbon produced. The knowledge created from such a study will help identify the optimum working conditions for roller compaction of different types of lactose.

2. Material and method

2.1. Materials

Three types of lactose powders were used in this study: anhydrous lactose (SuperTab21AN), α-lactose monohydrate (200M), and spray dried lactose (SuperTab11SD). All powders were supplied by DFE Pharma, Germany. These powders differ in their morphology and amorphous content due to the difference in manufacturing processes. Anhydrous lactose SuperTab21AN is produced from the crystallization of a supersaturated solution of lactose above 93.5 °C by roller drying [DFE Pharma, Germany]. The slow crystallization of a supersaturated lactose solution below 93.5 °C results in single crystals of α-lactose monohydrate 200M. Spray dried lactose SuperTab11SD is produced by spray drying a suspension of α-lactose monohydrate in a solution of lactose. Because of the fast drying process, the product consists of small particles of α-lactose monohydrate connected with amorphous lactose [DFE Pharma, Germany]. Scanning electron microscopy JEOL JSM-6010LA was used to obtain electron micrographs of the primary powders as shown in Fig. 1. It can be seen that the SuperTab11SD lactose particles are more spherical in shape in comparison with the other two types of lactose.

Antaris II FT-NIR (Thermo Scientific, USA) was used to measure the amorphous content of the three types of lactose used in this study. Near Infrared Spectroscopy (NIR) is a fast, non-destructive and non-invasive technique. All materials absorb NIR radiation at a specific region or wavelength. NIR can be used to determine the physical and chemical properties of a material [14]. Further details of the method of amorphous lactose quantification can be found in [15]. The amorphous content of each type of lactose was determined and can be seen in Table 1.

2.2. Powder preparation and properties

The particle size distribution of the primary powder for the three types of lactose (as-received) was measured, under dry dispersion, using Camsizer XT (Retsch Technology GmbH, Germany) which operates based on image analysis. Fig. 2 shows the particle size distribution for the three types of lactose used.

Powders were conditioned in a climatic chamber (Binder KMF 240 climatic chamber, Germany) at 25 °C and different relative humidity conditions (10%, 20%, 40%, 80% RH) for 3 days.

The flow properties of the primary powders at different RH values were measured using a ring-shear cell tester RST-XS.s (Dr. Dietmar Schulze, Germany). The powder flowability was described by the flow function coefficient (*ffc*). The flow function coefficient of the powder is calculated from the consolidation stress of the corresponding yield locus divided by the unconfined yield strength. The flow property of the powders at different RH values was measured using 5000 Pa normal load at preshear, and normal load at shear of 1500, 2750, and 4000 Pa. According to Jenike [16], powders have an extremely poor flowability when FFC $\leqslant$ 1, very poor for the range of 1–2, poor between 2 and 4, fair between 4 and 10 and a good flowability > 10.

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