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Rapid communication

Experimental studies on the effect of moisture content and volume resistivity on electrostatic behaviour of pharmaceutical powders

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ABSTRACT

Pharmaceutical powders are mainly organic materials and are likely to be charged due to repeated inter-particle and particle-wall contacts during industrial processes. This study experimentally investigated the effect of moisture content (ranging from approximately 1.8 to 30 wt.%) on tribocharging behaviour of pharmaceutical granules, as well as their apparent volume resistivity. The tribocharging behaviour of pharmaceutical granules was investigated using a rotating device and apparent volume resistivity was measured in a conventional volume resistivity test cell. Additional measurements were performed on individual ingredients, each having the same moisture content as that of the granules, in order to investigate the effect of each single ingredient on the apparent volume resistivity of granules. In this work, the individual ingredients used for granules were: α-Lactose Monohydrate (α-LMH), Microcrystalline Cellulose (MCC), Hydroxypropyl Methylcellulose (HPMC), and Croscarmellose Sodium (CCS). The results showed that the specific charge of granules began to increase at the moisture contents below 5 wt.%, which can be referred as critical moisture content of granules. The apparent volume resistivity showed the same behaviour, indicating that the specific charge could be due to an increase in apparent volume resistivity of granules at reduced moisture content. Finally, it was shown that the apparent volume resistivity measured for granules was mainly affected by that of the α-LMH, the major component of granules accounting for 40 wt.%.

1. Introduction

More than 80% of the USA and Europe pharmaceutical market is represented by solid oral dosage (SOD) forms due to their relatively easy preparation techniques along with their enhanced physical and therapeutic properties (Perioli et al., 2012). Among the different types of SOD forms, tablets are the most applicable in the pharmaceutical industry as they have high manufacturing efficiency and can carry a wide range of doses (Ghori et al., 2015; Šupuk et al., 2012). A typical tablet manufacturing process involves several steps, including sieving, mixing, dispensing, mixing, granulation, drying, compression, etc., among which mixing and granulation have significant importance as having a homogenous mixture leads to a high-quality product with the correct amount of each ingredient. Granulation can be carried out in either dry or wet form. When the wet granulation method is chosen, wet granules need to undergo a drying process to remove undesired moisture. Fluidized bed dryers are considered to be one of the most commonly used drying methods especially for wet pharmaceutical granules, because of their providing a high rate of moisture removal, excellent mixing, rapid heat and mass transfer between phases, a large capacity of production and low capital cost (Briens and Bojarra, 2010; Law and Mujumdar, 2006). However, continuous particle–particle and particle-vessel wall contacts provide a favorable venue for electrostatic charge generation, known as "tribocharging", inside fluidized beds (Mehrani et al., 2005; Moughrabiah et al., 2009; Sowinski et al., 2010). Particle segregation, possible variations in the amount of active pharmaceutical ingredients (APIs) and excipients and subsequent reduction in final product uniformity, inter-particle cohesion and particle-vessel wall adhesion, and electrostatic discharge which might result in explosion under some conditions, are generally the problems associated with tribocharging (Ghori et al., 2015; Mehrani et al., 2005; Murtomaa et al., 2004; Sowinski et al., 2010; Šupuk et al., 2012).

In the literature, studies on the tribocharging behaviour of pharmaceutical powders are mainly on dry base and in a single component or binary form (a mixture of two ingredients) (Ghori

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et al., 2015; Naik et al., 2016a, 2016b, 2015; Šupuk et al., 2012; Watanabe et al., 2007). To the best of our knowledge, limited efforts have been placed to investigate their tribocharging behaviour in the granular form. In our recent work (Taghavivand et al., 2016), it was observed that during the drying process in a fluidized bed, electrostatic charges began to accumulate when the moisture content dropped below a certain value, approximately 5 wt.%. It was speculated that pharmaceutical granules became less conductive due to reduced surface moisture. However, conductivity of pharmaceutical powders was not quantified with changing moisture content. In practice, resistivity or volume resistivity is often used as an indicator of material electrical conductivity. A material with high resistivity indicates that electrical static charges are not easy to dissipate once this material is charged. In the literature, there is a lack of experimental data demonstrating the links between conductivity changes of pharmaceutical powders and electrical charge generation. Therefore, objectives of the present work were to quantify conductivity of pharmaceutical powders at various moisture contents by measuring volume resistivity and correlate them with charge generation when moisture content was reduced. In order to achieve the aforementioned goals, the experimental work was conducted in two parts.

In the first part, tribocharging ability of pharmaceutical granules was measured in a rotating device with a contact surface made of stainless steel. The granules were prepared at different moisture contents to understand the effect of moisture content on tribocharing behaviour. Subsequently, the volume resistivity of granule samples their individual ingredients were investigated in the second part.

2. Material and methods

2.1. Experimental set up for electrostatic charge generation tests

The experiments for measuring the electrostatic charges generated by simultaneous contact and friction between pharmaceutical granules and a stainless steel container were carried out in a rotating device as shown in Fig. 1(a). The experimental set up consisted of a rotating device (AC-1, Asahi-rika corp., Japan) equipped with a speed controller, a metal container (stainless steel, 70 mm in diameter, 90 mm in length), a Faraday cup with an inner cup diameter of 100 mm and a height of 100 mm, and an outer cup with a diameter of 150 mm and a height of 140 mm, a timer, an electrometer (6514, Keithley, USA), and a DC corona type electrostatic ionizer with an input voltage of 24 kV (KD-740B, Kasuga Denki, Japan).

For the tribocharge generation tests, 5 g of granule samples were added to the metal container and agitated on the rotating device with a rotation speed of 125 rpm for 300 s, under which tribocharging behaviour was found to reach equilibrium. The stainless steel container was grounded electrically. The specific charge, q (nC/g), of the granule samples was obtained by dividing

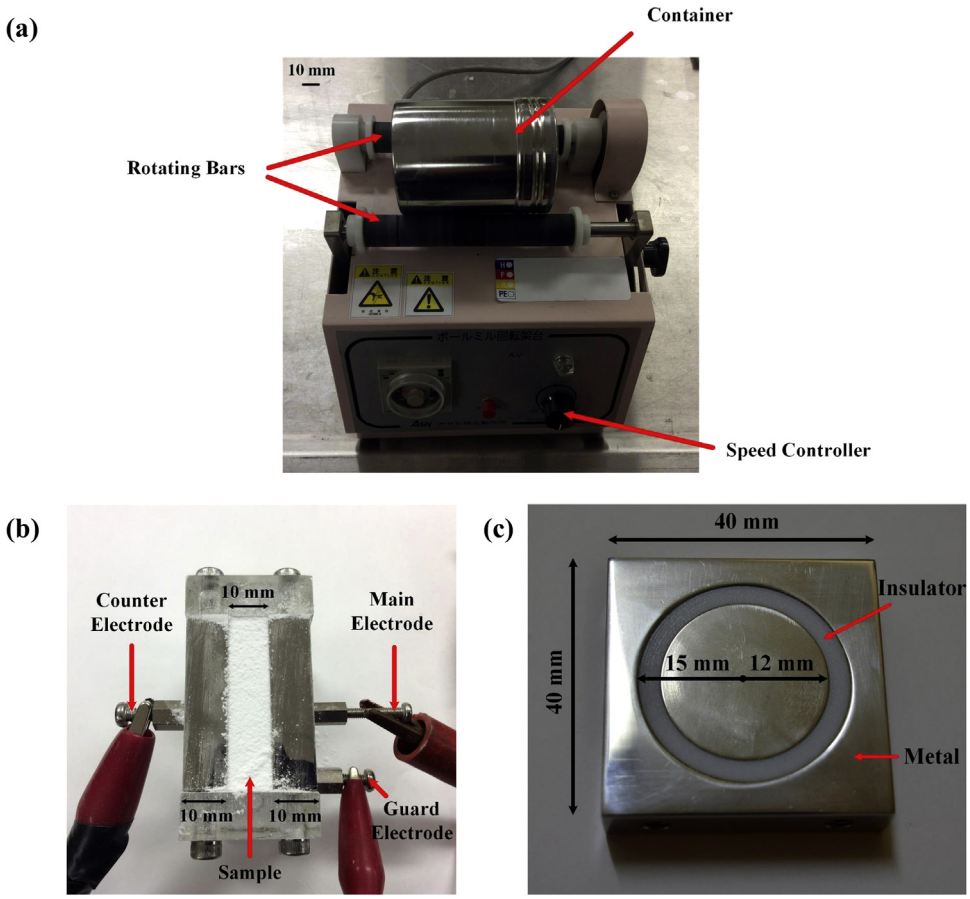

Fig. 1. (a) The rotating device and the container used in this study; (b) Top view of the volume resistivity test cell; (c) Inner view of the main electrode along with detailed dimensions.