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Glidant effect of hydrophobic and hydrophilic nanosilica on a cohesive powder: Comparison of different flow characterization techniques

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ABSTRACT

The methods used for flow characterization of a powder mass include the angle of repose (AOR), Carr index (CI), and powder flow tester (PFT). The use of nanosilica as a flow modifier (glidant) is very common in industry. This study aims to compare the glidant effect of hydrophobic and hydrophilic silica on a poorly flowable active pharmaceutical ingredient (ibuprofen) by different flow characterization techniques. Different percentages (0.5, 1.0, and 2.0 wt%) of both types of mixed silica–ibuprofen powders were evaluated by the AOR, CI, bulk density, and PFT. The flow factor, effective angle of friction, and cohesion were determined to explain the bulk powder properties. The results show that different types of silica show different levels of flow property improvement, but the techniques do not equally discriminate the differences. Hydrophobic silica results in better improvement of the flow property than hydrophilic silica, probably because of its better surface coverage of silica on the host particles. Change of the bulk density with applied pressure was significant for the different powders. This study demonstrates that combining several characterization methods provides a better understanding of bulk powder flow properties with respect to powder–process relationships than a single flow indicator.

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Introduction

Handling and processing of dry powder are fundamental operations in many industries, such as food, ceramics (Kojima & Elliott, 2013), and pharmaceuticals (Aulton, 2007). Handling of fine cohesive powder is very common in the pharmaceutical industry, where the flow properties of the powder usually have a major influence on product performance. For example, improper flow of a powder may cause variation in the tablet weight or non-uniformity of the weight during capsule filling (Lachman, Lieberman, & Kanig, 1986). Cohesive powders tend to agglomerate because of strong interparticle attraction forces. van der Waals forces are the main cohesive forces between fine powders (Li, Rudolph, Weigl, & Earl, 2004). Agglomeration of particles inhibits proper flow of the powder through the hopper when bulk powder handling is required. Therefore, knowledge of the powder behavior during bulk handling or flow is essential for processing operations with cohesive pharmaceutical powder.

Characterization of powder flow is important to ensure product performance in the pharmaceutical industry as well as to design a hopper through which powder can flow. Different methods can be used to characterize a powder mass based on its flow properties. These methods include compendial methods such as the angle of repose (AOR), determination of the bulk and tapped density, the Carr index (CI), and the Hausner ratio (HR) (Shah, Tawakkul, & Khan, 2008; Thalberg, Lindholm, & Axelsson, 2004; USP, 2011). The results of these methods are used for quality control and comparison or ranking of the powder mass in terms of the flow properties. Despite these methods being simple and straight forward in terms of execution and result interpretation, they lack reproducibility, predictability, sensitivity, and correlation between the derived data and the actual flow behavior. These limitations have created the demand for development of other advanced methods for flow characterization (Ding, Liu, & Bradley, 2012; Leturia, Benali, Lagarde, Ronga, & Saleh, 2014). The shear cell method for measuring powder flow properties is a popular and convenient way to characterize powder flow under shear. Application of the Jenike flow function and the corresponding flow index determined by a shear flow tester is a widely accepted measure of powder flow in industry (Althaus & Windhab, 2012; Emery, Oliver, Pugsley, Sharma, & Zhou, 2009). The flowability of a powder depends on several factors (Rios, 2006):

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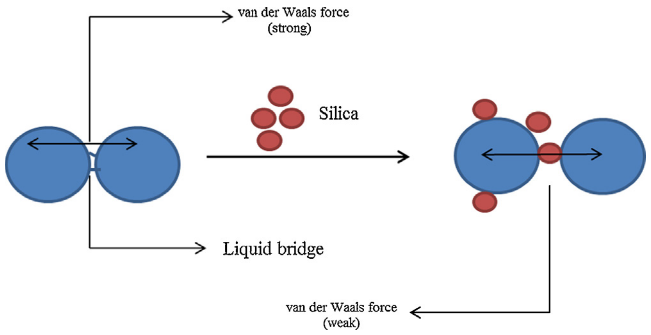

Fig. 1. Schematic of the arrangement of host particles and glidant after proper mixing.

- The particle properties such as particle size, density, and shape. Small and irregular shaped particles usually have poor flow properties.
- The bulk powder properties such as the bulk density, size distribution, cohesion, and adhesion forces acting on the powder.
- Environmental factors such as temperature and humidity.
- The nature and state of powder compaction.

In industrial operations, powders are subjected to different conditions, such as fluidization, mixing, and compaction. In each situation, the same powder may act differently in terms of flowability, especially cohesive powder. Accordingly, no single test can be used to predict the flow behavior of bulk powder in all practical situations. As a consequence, different flow characterization methods are combined to provide better insight into the flow properties of a powder. The results obtained from different flow characterization tests need to be combined to obtain a better understanding of the powder behavior considering bulk flow during different unit operations. This approach is attracting increasing interest of researchers working in particle and powder sciences (Thalberg et al., 2004). In a recent study, Leturia et al. (2014) reported a comparison of flow property measurements from different (compendial and noncompendial) methods. Their observations revealed that different tests are suitable for different bulk powder conditions. For example, a shear tester is more suitable in packed-bed conditions, whereas HR determination is more suitable in free-surface conditions. Shah et al. (2008) explained that a powder rheometer is suitable for investigation of cohesivity and the caking nature, whereas HR or CI determination is suitable to determine the characteristics of a powder in free-flowing conditions. These studies show the need to evaluate flow properties by different methods depending on the nature of the powder sample. Although not completely inclusive, the shear cell tester is able to characterize a powder mass under consolidated conditions. It simulates the stress acting on the bulk solid during flowing through the hopper, and determines the relationship between the powder behavior and the stress (Schulze, 2008). This is also effective for designing a hopper for a particular bulk powder flow and scaling up operations.

As well as aeration and vibration, addition of a glidant or flow modifier is a common method to improve the flow properties of cohesive pharmaceutical powders. Once mixing homogeneity is achieved, the glidant is uniformly distributed throughout the powder mass and acts as a spacer between host particles. It therefore increases the distance between host cohesive particles and reduces van der Waals forces (Kojima & Elliott, 2013). van der Waals forces decrease with increasing distance between host particles. A relatively simple understanding of this theory was described by Zimmermann, Eber, and Meyer (2004). The shorter the distance between particles, the higher the van der Waals force (Fig. 1). When a small guest particle, such as a glidant or surface modifier, is positioned between two larger host particles (Fig. 1), the van der Waals force decreases. If the guest particle is displaced from the space between two host particles, the van der Waals force increases, which in turn affects the flow properties of the bulk powder. Fumed nanosilica is one of the most commonly used glidants or flow modifiers in the pharmaceutical industry. Apart from reducing van der Waals forces, fine silica particles also act as a flowability enhancer by adsorbing surface moisture from host particles (Jonat, Albers, Gray, & Schmidt, 2006). Using nanosilica as a surface modifier for cohesive powder by dry powder coating can also improve both the flow properties and drug dissolution (Chattoraj, Shi, & Sun, 2011; Zhou, Shi, Marinaro, Lu, & Sun, 2013). The use of nanosized silicon dioxide or nanosilica as a flow regulator, surface modifier, or glidant in bulk powder handling is widely accepted. Both hydrophilic and hydrophobic colloidal silicon dioxide are used in various pharmaceutical formulations. Hydrophilic silica contains silanol (–Si–O–H) groups, which can be converted to hydrophobic groups by reacting with dimethyldichlorosilane. Dimethylsilyl groups attach to the surface of silica particles by forming stable siloxane bonds, making the particles hydrophobic (Fig. 2) (Jonat, Hasenzahl, Drechsler, et al., 2004). Nanosized colloidal silica used as a glidant has a tendency to self-agglomerate because of strong attractive forces. Therefore, creating a uniform distribution of nanosilica throughout the cohesive powder mass is very important to achieve a good glidant effect. Because the attached functional groups differ in hydrophobic and hydrophilic silica, it is expected that the effect of each type of silica on different powders will also vary. Based on this hypothesis, a study was carried out by Kojima and Elliott (2013) to evaluate the effect of silica nanoparticles on fine powders. Their study of the force distribution among fine powder particles in the presence of different types and amounts of silica revealed a difference in the host particle cohesion behavior depending on the nature of the silica (i.e., hydrophobic or hydrophilic silica). However, this study was carried out using spherical polymeric microspheres as the host and it did not consider different compendial methods of flow determination. In another study, the glidant effect of hydrophobic and hydrophilic compacted colloidal silica on different pharmaceutical excipients was investigated by Jonat, Hasenzahl, Drechsler, et al. (2004). However, the study only used the normal and dynamic AOR for flow measurements. An extensive comparative study of the flow properties of hydrophobic and hydrophilic silica-containing microcrystalline cellulose determined by the AOR and bulk density was reported by Jonat, Hasenzahl, Gray, and Schmidt (2004). They found significant variation in the AOR with respect to the hydrophilicity of silica. Hydrophobic and hydrophilic silica have been used to coat ibuprofen (ibu) powder by comilling to improve the flow properties and bulk density of the drug (Mullarney et al., 2011). The study proposed a method for dry particle coating by comilling using nanosized guest particles for pharmaceutical powders. However, evaluation of the effect of different types of silica on the flow properties was not within the scope of the study. Apart from the abovementioned studies, there are no reports of comparative evaluation of the effect of hydrophobic and hydrophilic silica on flow property improvement of cohesive active pharmaceutical ingredients (APIs) involving flow measurements from different techniques.

The aims of this study are

- evaluation and comparison of the flow properties of hydrophobic and hydrophilic silica mixed with API powder under both normal and stressed conditions;
- comparison of and correlation between conventional methods for powder flow measurements, including the AOR, bulk and tapped density determination, and HR and CI determination, as well as nonconventional method like the shear flow tester.

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