

Title	Behaviour of magnesium stearate in continuous feeding
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Publication date	2016-11
Original citation	Peddapatla, R. V. G., Blackshields, C. A., Cronin, M. F. and Crean, A. (2016) 'Behaviour of magnesium stearate in continuous feeding', Proceedings of the 2016 AIChE Annual Meeting, San Francisco, 13-18 November.
Type of publication	Conference item
Link to publisher's version	https://www.aiche.org/conferences/aiche-annual-meeting/2016/proceeding/paper/233r-behaviour-magnesium-stearate-continuous-feeding Access to the full text of the published version may require a subscription.
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Item downloaded from	http://hdl.handle.net/10468/4997

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Behaviour of magnesium stearate in continuous feeding

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INTRODUCTION

In a pharmaceutical continuous process line, feeding powders constantly and accurately into downstream processing units is challenging ¹. Consistent feeding is particularly challenging for cohesive materials such as the powder lubricant, magnesium stearate (MgSt). Even small changes in the feedrate of powders being fed for a short period of time, could result in products falling off the specification limits². Hence, the initial feeding raw material step is important and must be monitored continuously to achieve consistency in feeding. Feeding of pharmaceutical excipients into continuous process lines is most commonly accomplished through Loss-In-Weight (LIW) or Loss-In-Volume (LIV) feeders which operate in gravimetric or volumetric mode ^{1,3}.

In this study the continuous feeding of magnesium stearate alone and as a component of a tablet blend was studied. Magnesium stearate was selected as it is the most commonly used powder lubricant in tablet processing, and variability in its properties can comprise tablet ejection compaction, and performance (hardness and dissolution)⁴.

The objectives of this study were

1. To identify how the physical attributes of four different grades of magnesium stearate affect its continuous feeding performance.
2. To identify the effect of continuous feeding rate on the compaction and properties tablets prepared from blends (with and without lubricant).

MATERIALS

Four different grades of magnesium stearate obtained from two different suppliers, hereafter referred to as samples 1-4.

METHODS

Magnesium Stearate characterisation

Physical properties such as powder flow, bulk density, % compressibility are analysed using Brookfield powder flow tester (PFT) and Laser Light Scattering (Malvern 3000) for particle size distribution

Blends Preparation

Two blends are prepared in double cone Erweka blender blended for 30 minutes @ 30 rpm. Magnesium stearate is added to one of the blend and blended for extra 1minute @ 30rpm Blend 1 composed of 90% microcrystalline cellulose PH200 and 10% metoclopramide HCl. Blend 2 composed of 89.5% microcrystalline cellulose PH200 and 10% metoclopramide HCl and 0.5% magnesium stearate.

Feeder setup and evaluation

Loss in weight feeder are designed to monitor the changes in the bulk density of the powder in the feeder hopper⁵. Powders are fed through a K-Tron MT12 feeder using self-cleaning screws with fine square screen in gravimetric mode. Magnesium stearate samples are fed using Coarse Concave Screws (CCS) with Fine Square Screen (FSqS) setup, with two different set points of 0.15kg/hr. and 0.25kg/hr. Both blends are fed at 3 different set points 0.2238kg/hr., 0.5594kg/hr. and 1.0069kg/hr. with Fine Concave Screw (FCS) & Fine Square Screen (FSqS).

Mass flow performance was measured independently using a K-Sample Test System for Gravimetric Feeders. The relative standard deviation (RSD %) was determined from data collected at 30 sec intervals over a 30 minute duration.

RESULTS AND DISCUSSION

Continuous feeding performance

Feed factor is the gravimetric speed equivalent for 100% screw speed with a specific screw and screen setting. It gives an indication of the max. feed rates that can be achieved for a powder with specific equipment set up. Table 1 shows the measured bulk density and feed factors for the 4 grades of magnesium stearate studied.

Table 1

Sample	Bulk Density (g/cm³)	Feed Factor (kg/hr)
MgSt Sample-1	0.255	1.9486
MgSt Sample-2	0.186	1.2784
MgSt Sample-3	0.203	1.3676
MgSt Sample-4	0.154	0.7635

Physical properties of magnesium stearate impact on gravimetric powder feeding behaviour. Samples feed factors are directly proportional to their bulk densities.

A measure of feed performance is the variability in quantity feed which is expressed as the relative standard deviation (RSD %). In this study weights were determined at 30 sec intervals for a duration of 30 minutes. The results for magnesium stearate alone and tablet blends are shown in Figure 1.

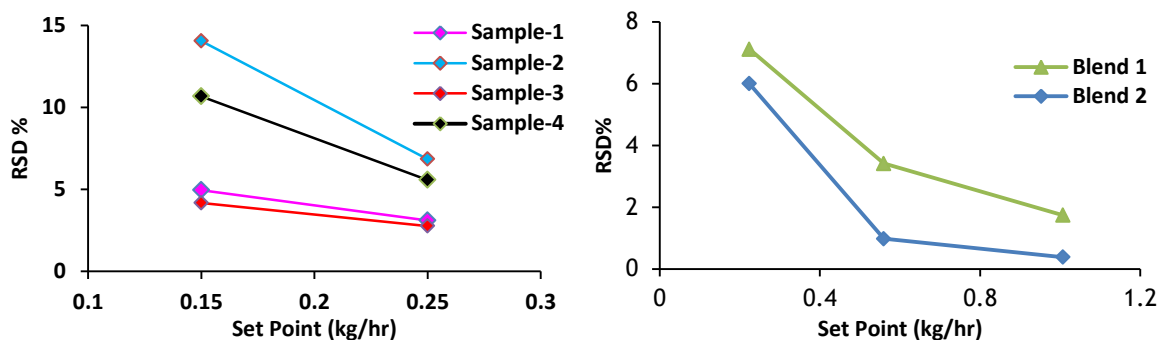


Figure 1: Feeding performance of magnesium stearate samples (left) and blends (right)

Magnesium stearate samples showed less variability at higher set points and greater variability at lower set points (Figure 1 left). Brookfield powder flow testing results showed magnesium stearate samples to exhibit very cohesive to cohesive flow behaviour and no relationship was seen between the feed variability and the measured flow function coefficient.

Blend 2 (which contained magnesium stearate) showed a lower % RSD compared to blend 1 at 3 different set points (Figure 1 right). Two blends fed at the lowest fed rate, 0.2238kg/hr, showed the highest variability.

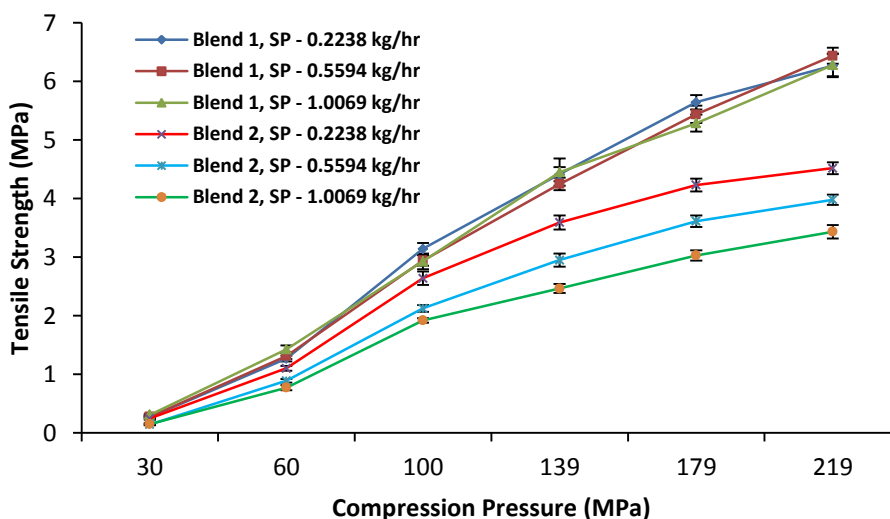


Figure 2: Tensile Strength profiles of both blends fed through the feeder at a range of fed rate set points.

There was no significant difference observed in tensile strength profiles fed at different set points for control blend 1, without magnesium stearate. Whereas the blend 2, with magnesium stearate, showed decrease in tablet tensile strength profiles upon feeding at higher set points (Figure 2). This may be due to increased mixing between the screws, as screws rotate with greater speeds upon increase in set point and would increase blending of the blend.

CONCLUSIONS

The bulk density magnesium stearate effected its feed factor - the higher the bulk density, the higher the feed factor achieved. While all magnesium stearate samples showed higher feeding variability at a lower feed rate, the difference was more pronounced for magnesium stearate samples 1 and 4. The physical properties responsible for differences in magnesium stearate feeding performance are currently being investigated.

The feeding rate of the blend containing magnesium stearate was seen to undermine its compaction properties. The higher the feeding rate the lower the tensile strength of the tablet produced. Future work will look at feeding rate impact on tablet dissolution.

ACKNOWLEDGEMENTS

Research funded by Pharmaceutical Manufacturing Technology Centre (PMTTC), an Enterprise Ireland, Irish Development Agency funded centre and Synthesis and Solid State Pharmaceutical Centre (SSPC) and Science Foundation Ireland (SFI) under grant number 12/RC/2275. PH200 was donated by FMC Corporation. K-Tron for support in use of MT12 micro feeder.

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