Compression Characterization and Lubricant Sensitivity of Orally Disintegrating Tablets Based on Ludiflash®

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Introduction

Ludiflash® – a new direct compressible excipient designed for orally dispersible tablets – was recently introduced into the market enabling quick development and cost-effective production of orally dispersible tablet via direct compression [1]. Because of its composition and physical structure it combines fast disintegration times with high hardness and a very smooth mouthfeel.

This study describes the impact of lubricant type and compression settings on tablet properties. As lubricants magnesium stearate and sodium stearyl fumarate, which differ strongly in lipophilicity were used. In addition the chosen placebo formulation was compressed on two tablet presses – one with and one without precompression roll. The goal was to optimize the composition and the manufacturing process of tablets based on Ludiflash®.

Methods

• Materials

Fast dispersible excipient based on mannitol, polyvinyl acetate and crospovidone (Ludiflash®, BASF SE),
Magnesium stearate (Bärlocher),
Sodium stearyl fumarate (Pruv®, Rettenmaier)

• Experimental methods

Tablet composition

Ludiflash®	294.0 mg
Lubricant	6.0 mg
Total mass	**300.0 mg**

Tablet form: 10 mm, round, flat bevelled edge

Table 1

• Manufacture of tablets

Ludiflash® and lubricant were blended in a Turbula blender (Bachofen) for 10 min and tabletted on Korsch PH 106 and Korsch XL 100 with increasing compression forces (3-25 kN, 40-350 MPa respectively). Humidity inside the tablet presses was adjusted to < 20% r. h.. All compression data and tablet properties were recorded and evaluated.

Results and discussion

The more hydrophilic sodium stearyl fumarate showed shorter disintegration times at all compression forces compared to the more lipophilic magnesium stearate, but surprisingly hardness was almost identical (Figure 1). The known lipophilizing effect of magnesium stearate usually should lead to a decreased hardness [2]. Considering both parameters, sodium stearyl fumarate is preferable for the manufacture of orally dispersible tablets, because it offers – when considering a maximum disintegration time of 30 sec – a broader compression force range and therefore harder tablets.

Regarding friability, there was almost no difference between sodium stearyl fumarate and magnesium stearate (Figure 2).

Figure 3 reveals, that the differences in disintegration time between sodium stearyl fumarate and magnesium stearate do not come from a strongly changed compressibility since the porosity curves are the same. Thus, improved wettability caused by sodium stearyl fumarate probably accounts for the differences in disintegration times.

Both lubricants are very effective as can be seen from the extremely low ejection forces (Figure 4). Surprisingly, there was no significant increase with increasing compression force.

Also tablet mass variations did not differ (0.53 – 0.80% with sodium stearyl fumarate; 0.46 – 0.70% with magnesium stearate).

Compression on the Korsch XL 100 compared to the Korsch PH 106 led to higher hardness values and at higher compression forces also to longer disintegrations times (Figure 5), which correlates with a reduced porosity (Figure 6). This effect was probably caused by the precompression step on the Korsch XL 100. All other compression parameters were within a similar range. In order to achieve a certain hardness and disintegration time the use of a precompression roll has to be taken into consideration.

Impact of lubricant type on hardness and disintegration of Ludiflash® tablets

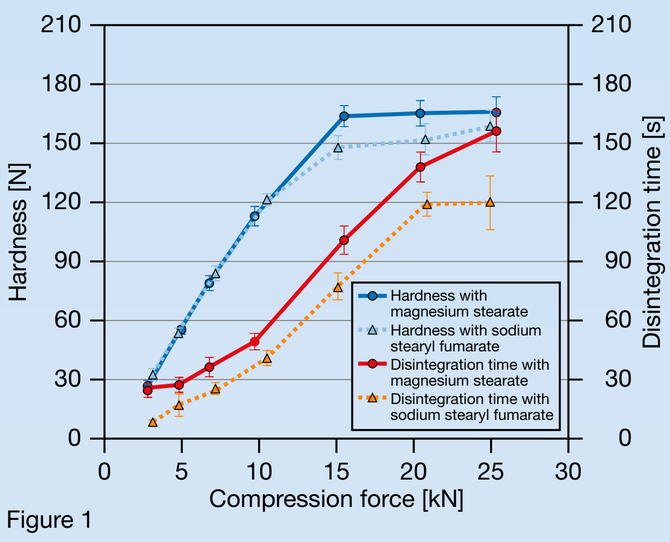

Figure 1

Impact of lubricant type on friability and hardness of Ludiflash® tablets

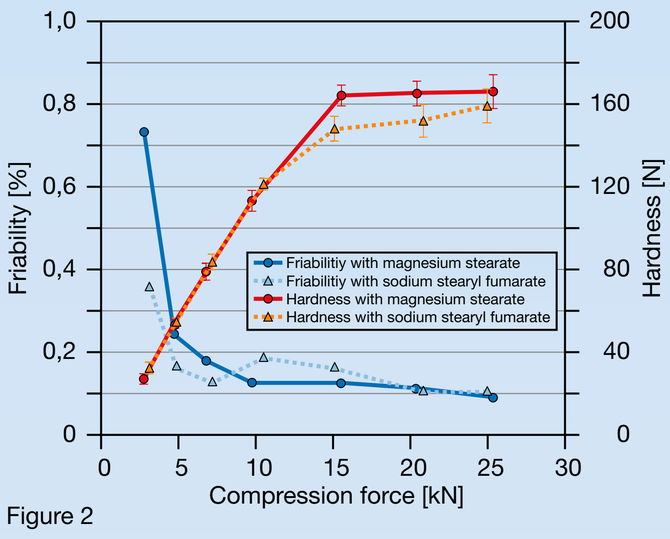

Figure 2

Impact of lubricant type on porosity and disintegration of Ludiflash® tablets

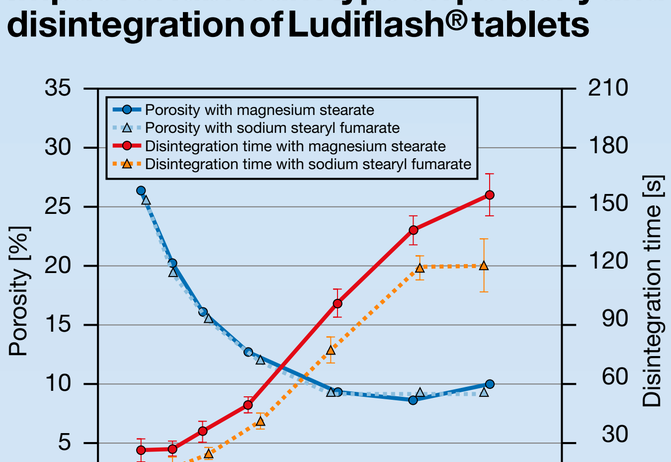

Figure 3

Ejection forces

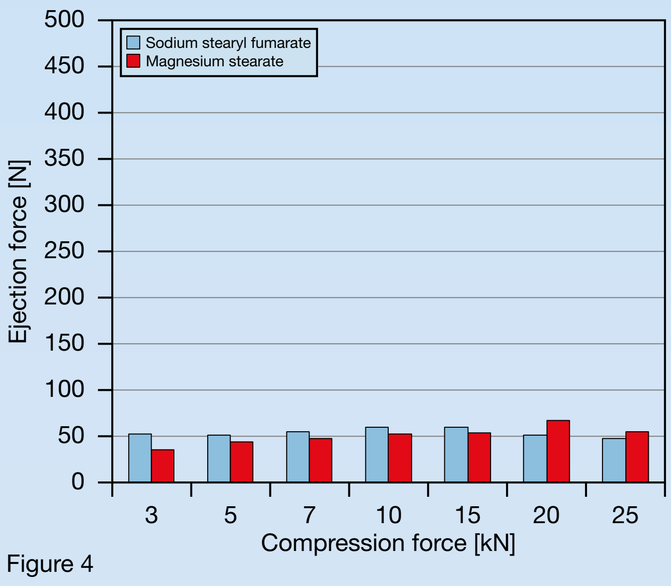

Figure 4

Comparison of tablet presses regarding hardness and disintegration

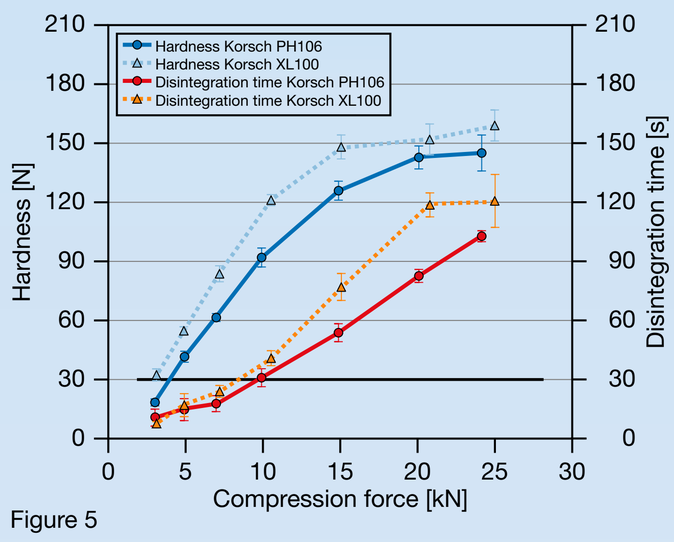

Figure 5

Comparison of tablets presses regarding porosity and disintegration

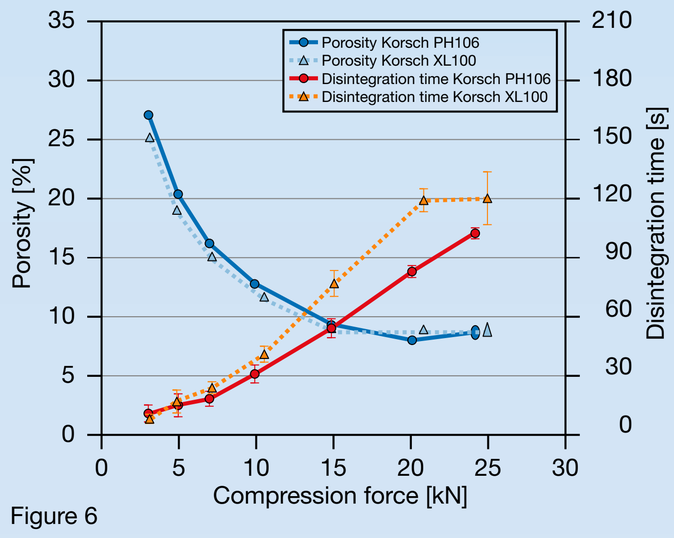

Figure 6

	Korsch XL 100	Korsch PH 106
Number of punches	8	6
Rotation Speed (rpm)	40	50
Tabletting speed (tablets/min)	320	300
Precompression force (kN)	0.2 – 0.6	–

Table 2

Conclusions

- **Sodium stearyl fumarate outperformed magnesium stearate in terms of hardness and disintegration time.**
- **The shorter disintegration times of sodium stearyl fumarate can be attributed to a better wettability and not to a change in tablet porosity.**
- **Precompression results in higher hardness and longer disintegration times and must be taken into consideration when switching tablet presses.**

References

[1] AAPS Congress November, 11th-15th 2007, San Diego, Poster T2093.
[2] A. Mehrotra, M. Llusa, A. Faqih, M. Levin and F. Muzzio, Int. J. Pharm. 336 (21), 284-91 (2007).

G-EMP/MD 216
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