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 properties, it enables shorter 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 strongly in lipophilicity were used. In addition the chosen placebo formulation was designed for orally dispersible tablets, because it enables quick development and cost-effective manufacturing process of tablets based on Ludiflash®.

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

- Experimental methods
  **Tablet composition**
<table>
<thead>
<tr>
<th>Excipient</th>
<th>Quantity (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ludiflash®</td>
<td>254.0 mg</td>
</tr>
<tr>
<td>Lubricant</td>
<td>6.0 mg</td>
</tr>
<tr>
<td>Total mass</td>
<td>300.0 mg</td>
</tr>
<tr>
<td>Tablet form</td>
<td>10 mm, round, flat bevelled edge</td>
</tr>
</tbody>
</table>
  
- 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 a compression precompression roll has to be taken into consideration. In order to achieve a certain hardness and disintegration time the use of a precompression roll has to be taken into consideration.

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).

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 disintegration 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.

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

Table 1
- **Impact of lubricant type on hardness and disintegration of Ludiflash® tablets**
- **Comparison of tablet presses regarding hardness and disintegration**
- **Impact of lubricant type on friability and hardness of Ludiflash® tablets**
- **Comparison of tablets presses regarding porosity and disintegration**
- **Impact of lubricant type on porosity and disintegration of Ludiflash® tablets**
- **Ejection forces**

**Figure 1**
Impact of lubricant type on hardness and disintegration of Ludiflash® tablets

**Figure 2**
Impact of lubricant type on hardness of Ludiflash® tablets

**Figure 3**
Impact of lubricant type on porosity and disintegration of Ludiflash® tablets

**Figure 4**
Ejection forces

**Figure 5**
Comparison of tablet presses regarding hardness and disintegration

**Figure 6**
Comparison of tablets presses regarding porosity and disintegration