Silymarin Direct Compression

Summary

Silymarin is a polyphenolic flavonoid derived from the milk thistle (Silybum marianum) which belongs to the Asteraceae family. Silymarin is high in polyphenols (also known as phytochemicals, i.e., biologically active compounds found in plants), one of the three major antioxidant groups. Extract of Silymarin is a more potent antioxidant than even tocopherol (vitamin E). The extract is taken as a dietary supplement to improve liver function and help prevent liver damage from toxins. The flowability of common Silymarin extracts is poor, but could be improved by adding PROSOLV® SMCC to produce a formulation suitable for direct compression.

Formulation

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Active content [mg]</th>
<th>mg/tablet</th>
<th>Contribution [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silymarin</td>
<td>35.0</td>
<td>35.0</td>
<td>16.05</td>
</tr>
<tr>
<td>PROSOLV® SMCC 50 (Silicified Microcrystalline Cellulose)</td>
<td>177.0</td>
<td>81.19</td>
<td></td>
</tr>
<tr>
<td>EXPLOTAB® (Sodium Starch Glycolate)</td>
<td>3.0</td>
<td>1.38</td>
<td></td>
</tr>
<tr>
<td>PRUV® (Sodium Stearyl Fumarate)</td>
<td>3.0</td>
<td>1.38</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>218.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Procedure

**Blending:**

The Silymarin was blended for 15 minutes with 50 % of PROSOLV® SMCC. The remaining 50 % of PROSOLV® SMCC was mixed with EXPLOTAB® for the same amount of time. Finally both mixtures were combined, PRUV® was added, and the powder was mixed for another 3 minutes. The powder mixture was ready for direct compression. The finished tablet requires coating.

**Equipment:**

- Tablet Press: Korsch EK 0 eccentric press, 8 mm punch
- Turbula Mixer: Type T2A
- Hardness Tester: Schleuniger 2E
- Disintegration Tester: Pharmatest Standard PTZ

**Tablet Characteristics**

- Tablet Weight: 218 mg
- Tablet Diameter: 8 mm
- Compaction Force: 12 kN
- Crushing Strength: 80 N

**Disclaimer:** The information provided is based on thorough research and is believed to be completely reliable. Application suggestions are given to assist our customers, but are for guidance only. Circumstances in which our material is used vary and are beyond our control. Therefore, we cannot assume any responsibility for risks or liabilities, which may result from the use of this technical advice.