Mebendazole Direct compression

Summary

Mebendazole belongs to the family of medications known as antihelminthics, i.e., antiparasitic agents used to eliminate intestinal tract worm infestations including hookworm, roundworm, threadworm, pinworm, ascariasis, hydatid disease, and giardia.

We developed a direct compression formulation with ANHYDROUS EMCOMPRESS®, PROSOLV® SMCC 90, and VIVASTAR® P as a flowability enhancer and binder and VIVASTAR® P as a disintegrant.

For further improvement of flowability, PROSOLV® SMCC 90 can be replaced by PROSOLV® SMCC HD 90.

Formulation

<table>
<thead>
<tr>
<th>Active content [mg]</th>
<th>mg/tablet</th>
<th>Contribution [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mebendazole</td>
<td>500.0</td>
<td>500.0</td>
</tr>
<tr>
<td>ANHYDROUS EMCOMPRESS®</td>
<td>71.9</td>
<td>10.3</td>
</tr>
<tr>
<td>PROSOLV® SMCC 90</td>
<td>100.6</td>
<td>14.4</td>
</tr>
<tr>
<td>VIVASTAR® P</td>
<td>12.7</td>
<td>1.8</td>
</tr>
<tr>
<td>Sodium Dodecyl Sulfate</td>
<td>5.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>9.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Total</td>
<td>700.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Procedure

Blending:
The API, ANHYDROUS EMCOMPRESS®, PROSOLV® SMCC 90, VIVASTAR® P, and Sodium Dodecyl Sulfate were blended for 20 minutes. Afterwards, Magnesium Stearate was added and the mixture and blended for 3 minutes. The powder mixture was ready for direct compression.

Equipment:
- Tablet Press: Korsch EK 0
- Turbula Mixer: Type T2A
- Hardness Tester: Schleuniger 6D
- Disintegration tester: Pharmatest Standard PTZ

Tablet Characteristics

- Compaction Force: 12 kN
- Tablet Diameter: 16 mm
- Tablet Weight: 700 mg
- Crushing Strength: 155 N
- Disintegration time: 120 s

Parameters

- Room temperature: 21.5 °C
- Rel. Humidity: 50 %