Diazepam
Direct Compression

Summary

Diazepam, better known under the brand name Valium™, is a benzodiazepine derivative. It is prescribed for the short-term management of moderate anxiety, tension, agitation, fear or aggressiveness. It is often used during certain medical procedures (e.g., surgery or dental work) to reduce anxiety. Dosages commonly range between 2 and 10 mg. This formulation is an example for a low-dosage active ingredient, suitable for direct compression.

Formulation

<table>
<thead>
<tr>
<th>Active content [mg]</th>
<th>mg/tablet</th>
<th>Contribution [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazepam</td>
<td>10.0</td>
<td>10.0</td>
</tr>
<tr>
<td>VIVAPUR® 12 (Microcrystalline Cellulose)</td>
<td>59.0</td>
<td>42.1</td>
</tr>
<tr>
<td>EMCOMPRESS® (Calcium Hydrogen Phosphate Dihydrate)</td>
<td>65.5</td>
<td>46.8</td>
</tr>
<tr>
<td>VIVASTAR® P (Sodium Starch Glycolate)</td>
<td>4.0</td>
<td>2.9</td>
</tr>
<tr>
<td>PRUV® (Sodium Stearyl Fumarate)</td>
<td>1.5</td>
<td>1.1</td>
</tr>
<tr>
<td>Total</td>
<td>140.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Procedure

**Blending:**
All excipients except PRUV® were blended for 30 minutes. Afterwards, PRUV® was added to the blend and mixed for an additional 3 minutes. The powder mixture was ready for direct compression.

**Equipment:**
- Tablet Press: Korsch EK 0, instrumented
- Turbula Mixer: Type T2A
- Hardness Tester: Schleuniger 2E
- Friability Tester: ERWEKA TAP
- Disintegration Tester: Pharmatest Standard PTZ
- Dissolution Tester: Pharmatest PTW 2
- Spectrophotometer: Cecil CE 1021

**Tablet Characteristics**
- Tablet Weight: 140 mg
- Tablet Diameter: 8 mm
- Compression Force: 22 kN
- Crushing Strength: 75 N
- Disintegration Time: 20 s
- Friability: 0.1 %
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**Dissolution Test:**

- **Dissolution Medium:** 900 mL 0.1 N HCl, 37°C, n=6
- Samples were taken after 1, 5, 10, 20, 30, and 60 minutes. The sample volume was 3 mL.
- The determination of the active ingredient was done by an UV-spectrometer at $\lambda = 242$ nm.

**Diagram 1:**
Typical dissolution profile of a Diazepam tablet. Produced according to the above formulation.

**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.