Ranitidine HCl
Direct Compression

Summary
Ranitidine HCl is a histamine receptor antagonist, which reduces the stomach's release of hydrochloric acid. It is used to prevent and treat ulcers of the stomach and duodenum, erosive esophagitis, and gastroesophageal reflux disease. Formulations for direct compression with an API content of more than 50% of the tablet mass can be made using VIVAPUR® 102 for good tablet hardness and VIVASTAR® P for short disintegration time. Oral tablets come in 150 and 300 mg dosages.

Formulation

<table>
<thead>
<tr>
<th>Active content [mg]</th>
<th>mg/tablet</th>
<th>Contribution [%]</th>
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</thead>
<tbody>
<tr>
<td>Ranitidine HCl</td>
<td>150.0</td>
<td>167.4</td>
</tr>
<tr>
<td>VIVAPUR® 102 (Microcrystalline Cellulose)</td>
<td>60.0</td>
<td>25</td>
</tr>
<tr>
<td>VIVASTAR® P (Sodium Starch Glycolate)</td>
<td>10.2</td>
<td>4.25</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>2.4</td>
<td>1.0</td>
</tr>
<tr>
<td>Total</td>
<td>240.0</td>
<td></td>
</tr>
</tbody>
</table>

Procedure
Blending:
Ranitidine HCl, VIVAPUR® 102 and VIVASTAR® P were blended to homogeneity for 15 minutes. Then a sieved mixture of Magnesium Stearate was added and mixed for another 5 minutes. The powder mix was ready for direct compression.

Equipment:
- Tablet Press: Korsch EK 0 eccentric press, 9 mm punch, biplane
- Turbula Mixer: Type T2A
- Hardness Tester: Pharmatest PTB 311
- Friability Tester: ERWEKA TAP
- Disintegration Tester: ERWEKA ZT 3
- Dissolution Tester: Pharmatest PTW II, with 6 vessels, flat blade paddle
- Spectrophotometer: Shimadzu UV-2101 PC

Tablet Characteristics
- Tablet Weight: 240 mg
- Tablet Diameter: 9 mm
- Compaction Force: 29 kN
- Crushing Strength: 110 N
- Disintegration Time: 315 s
- Friability: 0.9 %
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**Dissolution Test:**

<table>
<thead>
<tr>
<th>Dissolution Medium:</th>
<th>900 mL 0.1 N HCl, 37°C, n=6</th>
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<tbody>
<tr>
<td>Samples were taken after 5, 10, 20, and 30 minutes. The sample volume was 3 mL.</td>
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<td>The determination of the active ingredient was done by an UV-spectrophotometer at ( \lambda = 313 ) nm.</td>
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</tbody>
</table>

Diagram 1:
Typical dissolution profile diagram of a Ranitidine 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.