# 4282-007

## Enalapril Maleate Direct Compression

### Summary

Enalapril Maleate is an angiotensin converting enzyme (ACE) inhibitor used to treat hypertension and some types of chronic heart failure. Enalapril Maleate, is a poorly flowing API, and can be directly compressed using PROSOLV® SMCC 90 and EMCOMPRESS® as binders. Dosages of 5, 10 and 25 mg are common.

### Formulation

<table>
<thead>
<tr>
<th>Active content [mg]</th>
<th>mg/tablet</th>
<th>Contribution [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enalapril Maleate</td>
<td>10.0</td>
<td>5.1</td>
</tr>
<tr>
<td>PROSOLV® SMCC 90</td>
<td>93.7</td>
<td>47.8</td>
</tr>
<tr>
<td>EMCOMPRESS®</td>
<td>85.4</td>
<td>43.6</td>
</tr>
<tr>
<td>VIVASTAR® P</td>
<td>5.9</td>
<td>3.0</td>
</tr>
<tr>
<td>PRUV® (Sodium Stearyl Fumarate)</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Total</td>
<td>196.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

### Procedure

**Blending:**
Enalapril Maleate, PROSOLV® SMCC 90, EMCOMPRESS® and VIVASTAR® P were blended to homogeneity for 10 minutes. Then PRUV® was added and mixed for another 3 minutes. The powder mixture was ready for direct compression.

**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

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet Weight:</td>
<td>195 mg</td>
</tr>
<tr>
<td>Tablet Diameter:</td>
<td>8 mm</td>
</tr>
<tr>
<td>Compression Force:</td>
<td>18 kN</td>
</tr>
<tr>
<td>Crushing Strength:</td>
<td>110 N</td>
</tr>
<tr>
<td>Friability:</td>
<td>0.03 %</td>
</tr>
<tr>
<td>Disintegration Time:</td>
<td>15 s</td>
</tr>
</tbody>
</table>

### Disclaimer:
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