QUALI-V®
THE PREFERRED CHOICE FOR PHARMACEUTICAL SOLID ORAL DOSAGE FORMS

QUALI-V® HPMC CAPSULES, THE BEST ALTERNATIVE TO GELATIN

- Quali-V® HPMC capsules are equivalent in their dissolution profile to traditional hard gelatin capsules, with a similar disintegration time¹ and release properties², proving identical in-vivo performance behavior.

- While gelatin capsules undergo cross-linking at high temperature or high relative humidity³, such conditions do not affect the Quali-V® HPMC dissolution profile, as these capsules are chemically stable.

- In addition to having a lower moisture content (4.0%-6.0%), Quali-V® HPMC capsules demonstrate better performance than gelatin capsules in terms of brittleness. The moisture content of Quali-V® can be reduced minimizing significantly the occurrence of brittleness⁴ that takes place when drying gelatin capsules below a certain threshold.

- Moisture has more influence on static electricity in gelatin capsules than in Quali-V® HPMC capsules⁵.

**JP 1st (pH 1.2)** 40°C - RH 75% (6 months)

**JP 1st (pH 1.2)** 60°C (1 week)

**JP 1st (pH 1.2)** 30°C - RH 60% (1 year)

*Capsule fill formulation: Acetaminophen 35 mg, Lactose 280 mg, Croscarmellose 35 mg
Fill weight: 350 mg (Size 1 capsule)
Dissolution test method: Paddle at 50 rpm*
**QUALI-V® CAPSULES, SUPERIOR PROPERTIES FOR HYGROSCOPIC DRUGS**

- Quali-V® capsules *maintain their physical stability* when filled with hygroscopic materials or are exposed to low relative humidity conditions. They also hold many types of formulations: powders, pellets, tablets, semi-solids and non-aqueous liquids.

- Quali-V® capsules are proven to be *more resistant to breaking and fracturing* at very low relative humidity (12% RH), as they are *more elastic*.

**BRITENESS TESTER (QUALICAPS®)**

**CAPSULE BRITENESS IMPACT TEST (EMPTY CAPSULE; N=30)**

<table>
<thead>
<tr>
<th>Capsule</th>
<th>Tensile strength [N]</th>
<th>Elongation at break (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quali-V®</td>
<td>165 ± 16</td>
<td>14.6 ± 2.4</td>
</tr>
<tr>
<td>HPMC with no gelling agent</td>
<td>153 ± 15</td>
<td>9.7 ± 0.8</td>
</tr>
<tr>
<td>Quali-V®</td>
<td>172 ± 21</td>
<td>11.1 ± 2.0</td>
</tr>
<tr>
<td>HPMC with no gelling agent</td>
<td>119 ± 40</td>
<td>8.5 ± 1.2</td>
</tr>
</tbody>
</table>

(RH 45% - 50% (ambient humidity), RH 12% (low humidity), size 1, N=10, Average ± SD)

- Superior resistance to breaking and superior de-blistering performance make Quali-V® capsules the *ideal option to safeguard encapsulated products during long-term storage*, even in less than ideal conditions.

**QUALI-V® CAPSULES, THE PERFECT CHOICE FOR RAPID DISSOLVING DRUG PRODUCTS**

- Quali-V® capsules demonstrate a very *rapid and predictable dissolving drug product profile* where 85% of the API is released in the first 15 minutes at different pH levels.

- Quali-V® capsules show *high reproducibility of in-vitro performance* between manufactured lots.
• Quali-V® capsules have a faster release profile, with a shorter timeframe until first rupture, 3-4 minutes less than other HPMC capsules on the market. Quali-V® also shows quicker dissolution rates with less variation.

• Quali-V® capsules are specifically designed for oral pharmaceutical applications where dissolution properties are prioritized over mechanical properties to ensure a consistent dissolution profile in standard conditions.

**Quali-V® capsules**

**Designed to meet the demanding requirements of pharmaceutical industry**

- 100% plant-based and preservative-free, Quali-V® is acceptable for consumption within certain dietary and religious limitations. Quali-V® also responds to the clean label movement among today’s consumers.

- Pharmaceutical-grade quality. The manufacturing process is carried out following strict pharmaceutical criteria and certified according to ISO 9001 and ISO 14001. Drug Master Files for the US and Canada have been registered.

- Quali-V® capsules do not undergo any changes in physical and chemical performance throughout their 5-year shelf-life; all parameters meet the specifications during stability studies.

**Capsule fill formulation**: Caffeine 100 mg
**Capsole**: Size 1 capsule
**Dissolution test method**: Paddle at 50 rpm

**Quali-V® capsules for pharmaceutical applications**

- Purified water
- JP16 2nd (pH 6.8) + 9 g KCl (NON-USUAL CONDITION)

**Qualicaps® HPMC capsules for non-pharmaceutical applications**

- Purified water
- JP14 2nd (pH 6.8)
- JP17 1st (pH 1.2) + 9 g KCl (NON-USUAL CONDITION)

**References**
