Capsugel® | Lonza Pharma & Biotech

Good as gold.

Capsugel®

Vcaps® Plus capsules

The gold standard in HPMC capsules

Immediate release in-vivo performance bioequivalent to gelatin and consistent dissolution across changing pH and ionic strength.

- *Immediate release capsule*
- *HPMC capsule with no gelling agent*
- *Perfect for hygroscopic APIs*
- *Non-animal, vegan* friendly*
- *Cultural and religious acceptance globally*
- *Narrow weight variability*
- *Impressive resistance to heat and humidity*
- *Validated manufacturing experience*
- *Designed to improve product stability*
- *Made to reduce development timelines*

Regulatory acceptance: All primary components of Capsugel® Vcaps® Plus capsules are acceptable for use in pharmaceutical and dietary supplement oral dosage applications in the US, Canada, EU, Japan and Australia.

In addition, Capsugel® Vcaps® Plus capsules are certified Kosher by Ko, approved for vegetarians* by the Vegetarian Society and certified Halal by IFANCA.

* Transparent and colored empty capsules are vegan certified. Empty capsules containing the colorant carmine are not vegan certified. Imprinted empty capsules are vegan certified if imprinted with shellac free ink.

Made better. By science.™ **www.capsugel.com**

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Finally, a superior specialty polymer capsule with proven gelatin-like performance without cross-linking potential.

Capsugel® Vcaps® Plus capsules can optimize capsule disintegration for pharmaceutical products with the ability to release contents independent of pH and ionic strength of the test media. Made through an innovative thermo-gelation process, the capsule avoids the addition of gelling systems that can react to the pH or ionic strengths of dissolution media. An in-vivo study demonstrates that Capsugel® Vcaps® Plus capsules are equivalent to gelatin in terms of human pharmacokinetics profile.

Temperature Stability

An internal study showed no change in physical performance over extended exposure to a range of storage temperatures and relative humidity.

Long-Term Storage Stability

Internal studies showed no changes in color, transparency, loss on drying (LOD), disintegration, dissolution or filling performance at low temperatures, and no changes in disintegration, dissolution or mechanical performance at high temperatures.

Capsule Filling Machine Performance

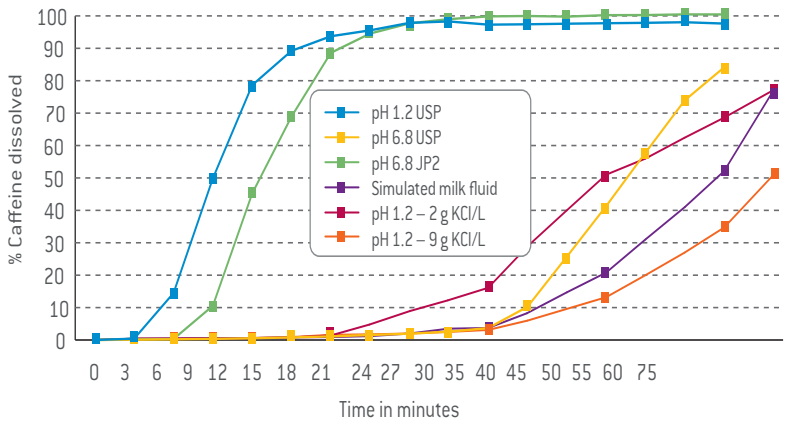
Performance trials on many common high-speed capsule filling machines indicate that Capsugel® Vcaps® Plus capsules, with their smooth and shiny finish, show better performance than HPMC capsules containing gelling agents, in terms of filling and rejection rate, and have a similar performance to gelatin capsules.

Effects of Moisture

Study results indicate that as a consequence of being less hygroscopic, moisture transfer from a Capsugel® Vcaps® Plus capsule to the encapsulated product could potentially be reduced, helping to maintain product stability. Also, since water does not act as a plasticizer for Capsugel® Vcaps® Plus, the capsules are less likely to break even in dry conditions, helping to maintain stability of products inside the capsule.

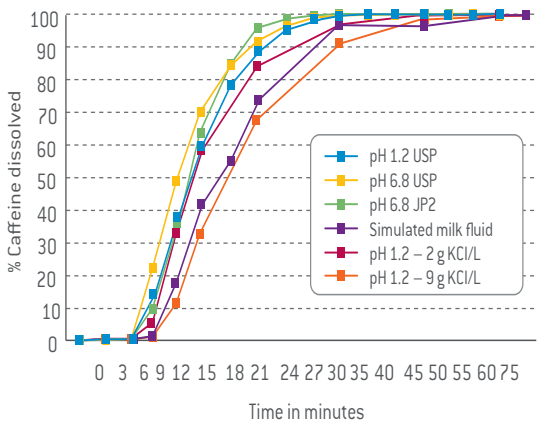
Secondary gelling systems create variability while Capsugel® Vcaps® Plus capsules, without gelling agents, provide ionic and pH independence in dissolution.

Influence of gelling systems on HPMC capsules in dissolution testing



In-vitro dissolution of caffeine filled in hypromellose capsules produced with gelling systems

In-vitro dissolution of caffeine in Capsugel® Vcaps® Plus capsules



Caffeine *in-vitro* dissolution with various dissolution media exhibit pH independence with Capsugel® Vcaps® Plus capsules

For more information visit capsugel.com or contact us at:

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