

Vcaps® Plus HPMC Capsules for Powder Filling

Vcaps® Plus HPMC (hypromellose) capsules are the perfect choice when you need a non-animal capsule to meet stringent global pharmaceutical standards, batch-to-batch quality and consistency on a commercial scale.

Ensuring Optimal Delivery of Critical Drugs

Using a proprietary manufacturing process that eliminates the addition of gelling agents, Vcaps Plus HPMC capsules expand the range of capsule applications.

Well Suited for Moisture-Sensitive Formulations

With low moisture content (see Figure I), Vcaps Plus HPMC capsule applications include:

- Formulations that contain hygroscopic materials, including dry powder inhalers.
- Formulations with active ingredients that are moisture sensitive.

Excellent Machinability and Mechanical Stability

An exclusive capsule design coupled with an elastic polymer structure enables high machine efficiencies.

- Extensive field testing on a wide array of capsule filling and blister packaging equipment confirms robust commercial performance.
- Vcaps Plus HPMC capsule shells are not affected by moisture. Even in low humidity environments, they maintain their elasticity and ability to resist mechanical breakage.

Resistant to Cross-Linking

With a well-characterized and stable polymer structure, Vcaps Plus HPMC capsules offer reduced potential for cross-linking. And unlike gelatin, they will not cross-link with aldehydes. (See Figure II)

Globally Accepted Pharmaceutical Formulation

The non-animal components of the Vcaps Plus HPMC capsule formulation are accepted for pharmaceutical use in all major global markets. TSE certification is not required, reducing the resources required for regulatory filings and international shipping and customs documentation.

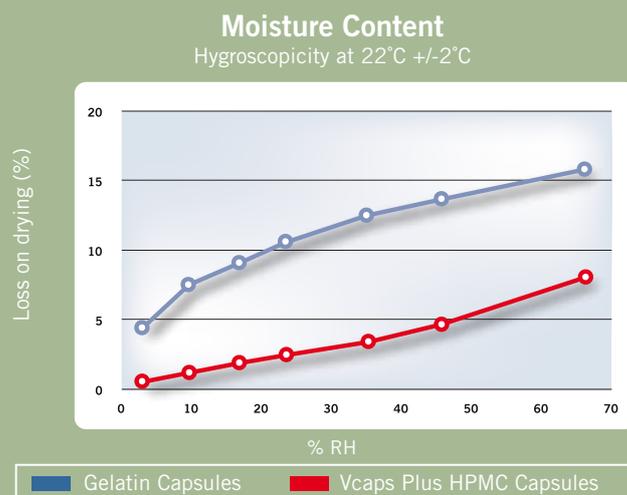


FIGURE I

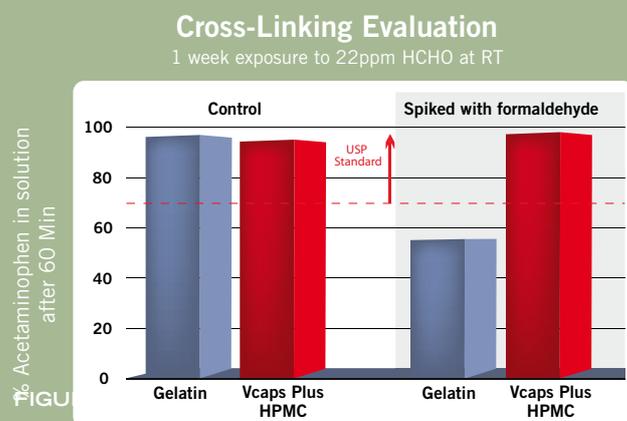


FIGURE II



A Simpler Approach Yields a New Dimension in Performance

The chemical simplicity of Vcaps Plus HPMC capsules, which contain just two primary components (HPMC and water), can yield important advantages.

Elimination of Gelling Agents Reduces Interference with Analytical Assays

With no added gelling agents or ionic gel promoters, Vcaps Plus HPMC capsules can:

- Avoid interactions with components of the formulation.
- Reduce interference with buffers used for *in vitro* dissolution studies.
- Minimize interactions with dietary components of fed *in vivo* studies.

pH-Independent *in vitro* Dissolution

Vcaps Plus HPMC capsules offer prompt disintegration (3–4 minutes; USP Method).

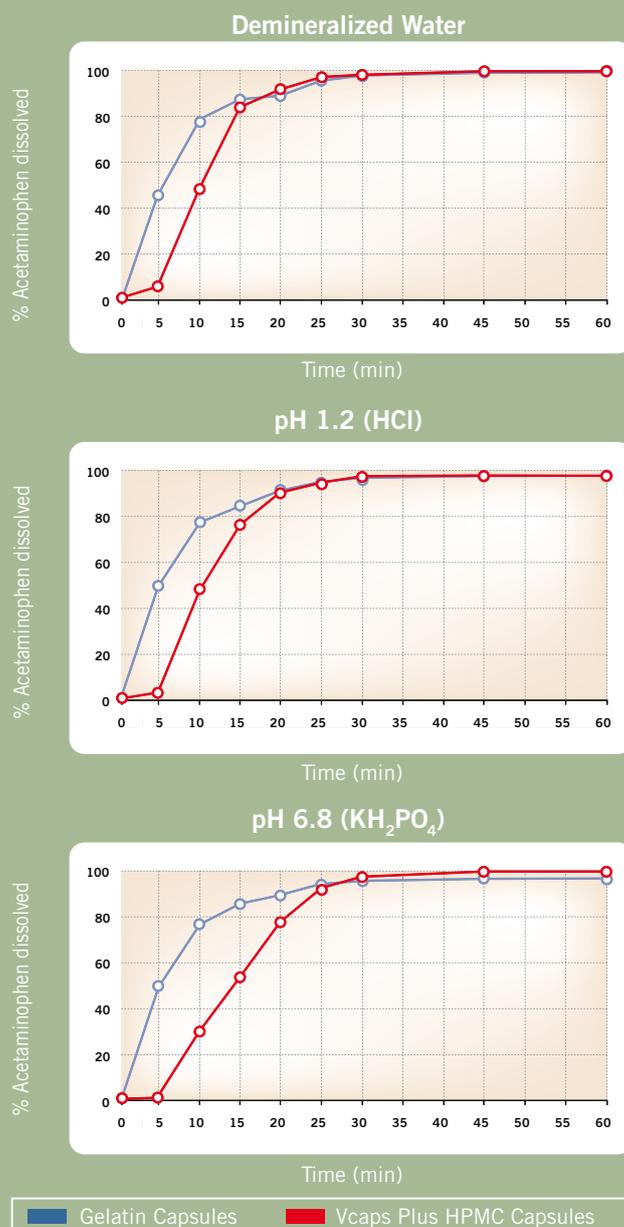
In vitro studies provide dissolution end points that closely match gelatin capsules across the relevant pH range. (See Figure III)

Gelatin-Like Appearance and Greater Patient Compliance

With an elegant high gloss surface, Vcaps Plus HPMC capsules appear identical to gelatin, and use a similar array of colorants including globally-approved iron oxide pigments.

With no animal-derived components, a wider array of global dietary needs and preferences are met.

In vitro Dissolution Profiles



USP Test Protocol: Capsules filled with formulated acetaminophen; Apparatus II (paddle, 50 rpm); 900 ml fluid at 37° C with buffers as indicated.

FIGURE III

Capsugel's Product Development Centers can help with compatibility testing, analytical testing and support for capsule filling trials.



For more information visit www.capsugel.com, send an e-mail to pharmaceuticaldevelopment@capsugel.com or call +33 3 89 20 57 25

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