



Through the blend of polymer science and capsule engineering, Capsugel has developed a line of functional capsules that provides the industry with the first viable alternative for achieving enteric protection and delayed release without functional (enteric) coating. Intrinsically enteric capsule technologies are key product design and development tools within the Capsugel targeted delivery technology suite, and can be coupled with a range of additional enabling technologies to meet the bioavailability and pharmacokinetic profile required for your drug product.

Vcaps® Enteric is a fully compliant capsule technology that can simplify and accelerate the development of drug products requiring enteric protection and/or delayed release. The pharmaceutical grades of cellulosic derivatives used in Vcaps Enteric are approved and have extensive market precedence for use in providing enteric protection. And Vcaps Enteric capsules have been evaluated in-vitro and in-vivo across a number of compounds, which has proven full compliance with relevant European, Japanese and US Pharmacopeia monographs.

### Broad Applications

Vcaps Enteric has a number of potential applications for functionality, product development, branding and intellectual property protection.

### Product Differentiation

As a proprietary technology – and the only viable alternative to enteric coating — our intrinsically enteric capsule technologies offer potential product differentiation, life cycle management, and intellectual property opportunities.

### Rapid Product Development

By removing the need for enteric coating, intrinsically enteric capsule technologies also offer tremendous potential in early stage product development, greatly simplify formulation and process development — as well as scale-up and validation. Independent analysis has indicated savings of more than 9 months in Phase III readiness by eliminating development, scale-up and validation steps associated with enteric coating.<sup>1</sup>

### Product Functionality

Improving tolerability of APIs that cause gastric irritation

Protecting APIs against degradation in the gastric environment (formulation-dependent, typically APIs with low to moderate acid sensitivity)

Achieving delayed or targeted release in the small intestine



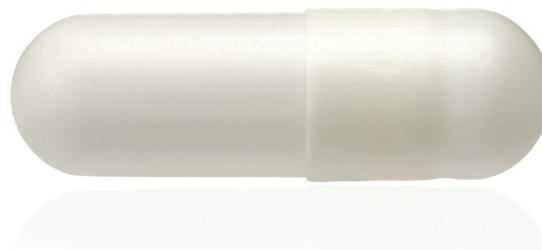
1. H2 Pharma Consulting Ltd, Dr. Hiep Huatan PhD, BPharm, MRPharmS, Bearsted, Maidstone, UK

## Product description

Two-piece enteric hard capsule

Manufactured with pharmaceutical-grade cellulosic enteric derivatives (HPMCAS, HPMC)

Size # 0, white opaque standard (other capsule sizes and colors available upon request)



## Prototyping

The Vcaps Enteric can be used to greatly simplify and accelerate prototype development and rapid *in-vivo* testing of products requiring modified or targeted release to the upper GI tract.

Eliminate coating system preparation and application steps

Enable rapid screening and optimization of enteric performance

Remove dependency of enteric functionality with process variability

Obviate need for process development of the enteric coating step, process scale-up and validation

## Regulatory Status

Contains commercial polymers used in coating and other pharmaceutical applications for more than 20 years

Complies with relevant European, Japanese and US Pharmacopeia monographs

## Water content: Less than 6%

Storage recommendations: 15–25° C & 35–65% RH, in moisture-tight packaging

Robust performance over time and ICH conditions

Learn more about how Capsugel's Vcaps Enteric can accelerate your development programs and provide for innovative product design.

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