

Capsugel® Enprotect® Capsule

A unique platform for enteric delivery

Capsugel® Enprotect® capsule enables enteric delivery without the need for a post-filling coating step. This helps protect your sensitive active pharmaceutical ingredients (APIs) during production and accelerates your manufacturing process.

Lonza

Capsules & Health
Ingredients



What is Lonza's Capsugel® Enprotect® Capsule?

Capsugel® Enprotect® capsule has a functional hard shell that provides targeted enteric delivery of an API payload through a combination of polymer science and capsule engineering.



Acid resistant up to pH 6.0



**Ready-to-use,
customizable capsule**



**Grand winner, Medicine Maker
Innovation Awards 2023***

*Source: <https://themedicinemaker.com/discovery-development/innovation-awards-the-grand-winner>

Advancing oral enteric delivery

With Capsugel® Enprotect® capsule, you can meet compendial enteric delivery requirements, while enabling accelerated development and commercialization processes.

Enabling new formulation and therapy modalities

- No API exposure to heat and solvents
- Consistent enteric release to the jejunum/ileum region, both with in vitro tests and trials in healthy volunteers, in both fasted and fed conditions
- A wide range of sizes

Enhancing manufacturing and production efficiency

- One-step filling with no post-filling coating or sealing required
- High machinability and faster production

Establishing compliance and consistency

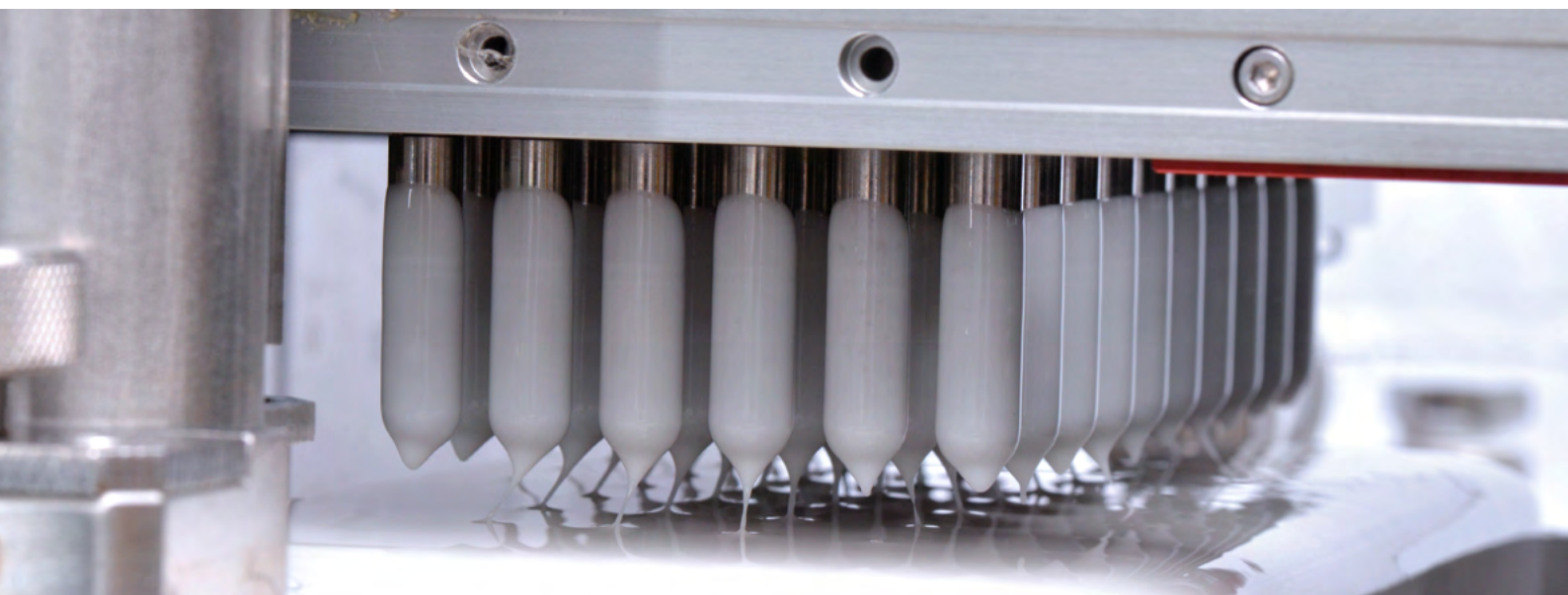
- Leak-free Coni-Snap® secure closure and consistent dissolution
- Customized print

How does Capsugel® Enprotect® Capsule work?

Capsugel® Enprotect® capsule is a bi-layered shell of two polymers: an HPMC inner layer (aligned to hard capsule manufacturing process and mechanical properties), and an HPMC-AS outer layer (which achieves enteric dissolution).

The unique manufacturing platform technology produces capsules with these two layers, while maintaining standard dimensions.

Importantly, this technology obviates the need for functional enteric coating to protect sensitive APIs because they are filled directly into the capsule without further downstream processing. Capsugel® Enprotect® capsules are therefore a valid alternative to functional enteric coating.



Compendial test evaluation

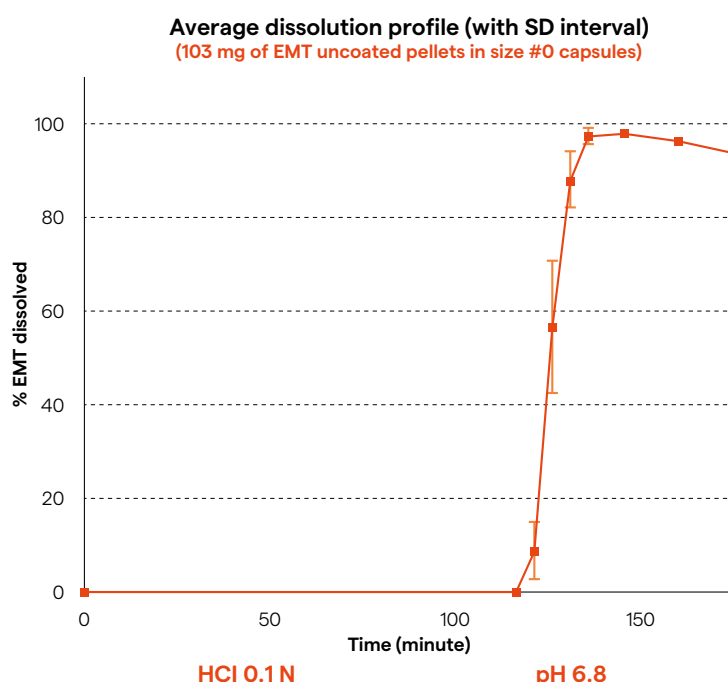
Dissolution performance

- Enteric performance according to USP monograph for *Esomeprazole Magnesium delayed-release capsules*
- Capsugel® Enprotect® capsules are intrinsically enteric even in highly detrimental scenarios

Disintegration performance

- Comply with requirements for delayed release (USP) and gastro-resistant (Ph.Eur) capsules:
 - to withstand an acid environment for 2 hours, then disintegrating within 1 hour in the buffer stage

Capsule performance: Enteric properties/dissolution



Available capsule sizes and colors

Size	Color
Size 0	White/white; Swedish orange/Swedish orange (TiO ₂ -free)
Size 1	White/white
Size 2	White/white
Size 9 (for pre-clinical trials)	Natural transparent/natural transparent



Closure mechanism

Capsugel® Enprotect® capsules feature the Coni-Snap® secure closure design. The two-ring locking system prevents leaks and facilitates high-speed filling.



Stability in extreme conditions

Capsugel® Enprotect® capsules retained their enteric properties after twelve months' exposure to cold conditions down to -80°C (Internal Lonza study still in progress)



Excipient compatibility

Capsugel® Enprotect® capsules are compatible with standard solid phase excipients and can be used for development of powder-based enteric dosage forms.



Customization

Capsugel® Enprotect® capsules are available in a wide range of standard sizes. They can also be customized to your optimum dissolution profile and with a variety of colours to meet the needs of your brand.



Further technical details

For a full breakdown of the technical specifications of Capsugel® Enprotect® capsule, please refer to the **technical reference file**.

Or, to talk with one of our experts about how Capsugel® Enprotect® capsule can be customized to help support your drug development, contact us **here**.

Review and follow all product safety instructions.

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