Enabling a Healthier World

Lonza
Capsules & Health Ingredients

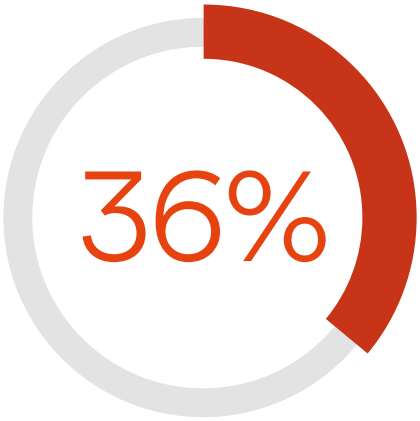
Capsugel® Enprotect® Capsule

First of its kind enteric technology

The microbiome market

In a rapidly growing market, microbiome-based therapies are in high demand, yet many are abandoned due to challenges in the drug development pipeline.

Quality and batch compliance



of the microbiome drug candidates that were in the drug development pipeline between 2018 and 2021, **failed due to inadequate delivery of the API**[1]

Estimated

$1.6 billion

market value of the global human microbiome market, including drugs, probiotics, prebiotics, foods, and diagnostic tests in 2028[2,3,4]

Expanding from $894 million in 2025

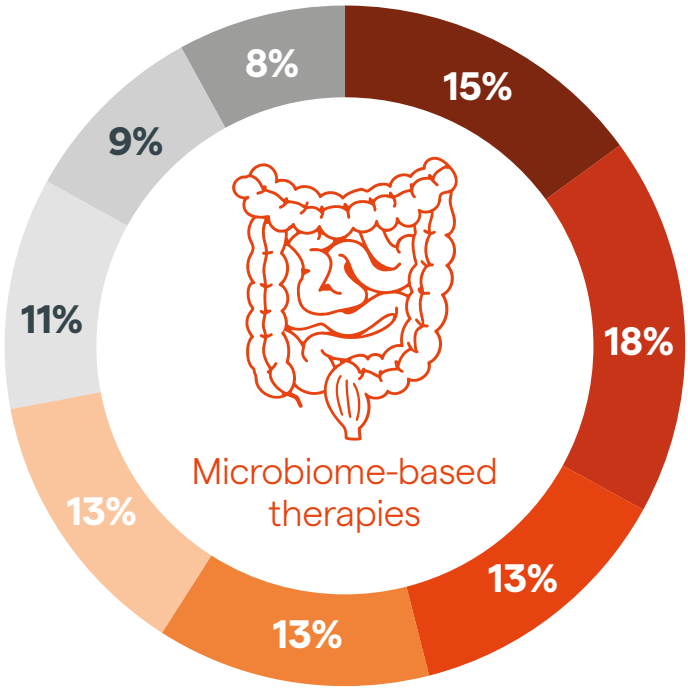
Today's microbiome market by the numbers

The majority of microbiome-based therapies under development today target, amongst others, diseases of the gastrointestinal tract, psoriasis and diseases that involve the gut–brain axis, such as Parkinson's disease and other neurological disorders, cancer and infectious disease, such as *Clostridium difficile* infections.

Currently over

3000

studies on the microbiome[4]

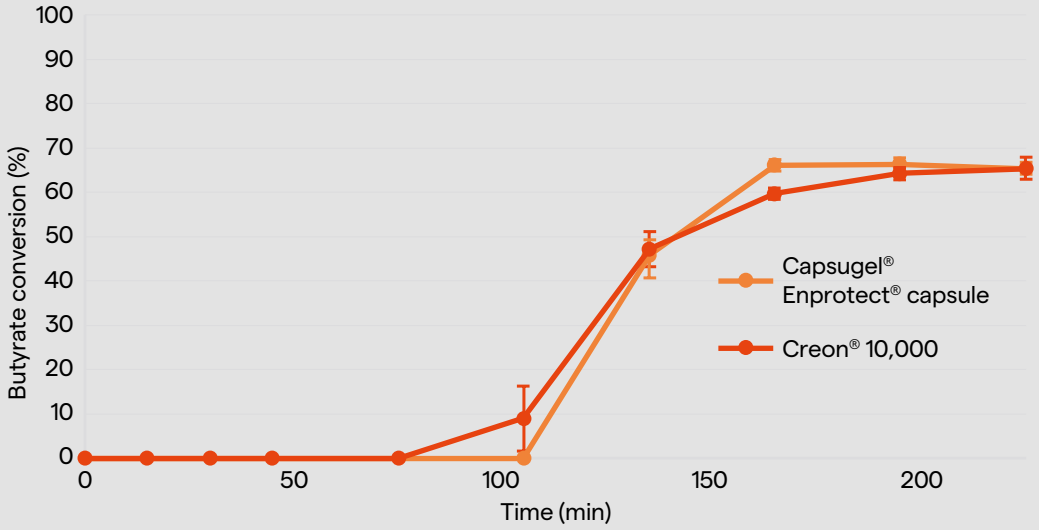


Delivering new drug modalities

Gastrointestinal delivery of acid-sensitive pancrelipase* was evaluated with Capsugel® Enprotect® capsule using an exocrine pancreatic insufficiency disease model. Proof of enzymatic activity was determined by measuring conversion of tributyrin to butyrate.†[5]

*Pancrelipase is a product containing a mixture of digestive enzymes (lipases, proteases and amylases) used to treat patients whose pancreas do not produce sufficient enzymes to properly digest dietary proteins, carbohydrate and fats, a condition called "exocrine pancreatic insufficiency"[6]

†SHIME®, Simulator of the Human Intestinal Microbial Ecosystem[5]



- The pancrelipase activity has been fully protected by the Capsugel® Enprotect® capsule, as the butyrate conversion rate of 66% is the maximum achievable for this enzyme
- Capsugel® Enprotect® capsule had a similar release profile, enzyme protection and efficiency as the Creon® (pancrelipase) 10,000 U capsule

Figure: Pancrelipase activity determined by measuring the conversion of tributyrin to butyrate

Capsugel® Enprotect® Capsule

Oral solid dosage form with first of its kind enteric technology

Building on the Capsugel® legacy of developing and launching innovative oral solid dosage forms, Lonza has developed a unique manufacturing process to build a **bi-layered capsule to assist in enteric delivery.**

Partner with us to meet compendial enteric delivery requirements and enable accelerated development processes.

Targeted enteric drug delivery

Acid **protection**

No post-filling coating required

Customizable and scalable

Capsule shown on right is the Swedish Orange-colored Capsugel® Enprotect® capsule in size 0, formulated with iron oxide and free from titanium dioxide

Coni-Snap® secure closure capsule design

Locking system provides leak-free containment enabling maximum delivery of API

Proprietary two-ring closure system facilitating high-speed filling processing and secure locking of capsule body and cap

HPMC and HPMC-AS polymers

Protects acid-sensitive APIs, preventing gastric irritation and allows for intestinal delivery

Provides acid resistance up to pH 6.0 with no need for banding or sealing

Rapid disintegration profile release (within 30 minutes) in the buffer stage (pH 6.8)

Bi-layered technology

Ensures targeted delivery of APIs to the distal small intestine without the need for post-filling coating excipients[7,8]

No post-filling coating or additional excipient helps to accelerate drug development processes, inducing fast first-in-human timelines

Create your ideal capsule/get support

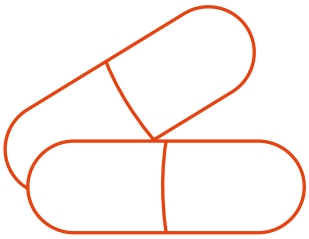
Customize your capsule to meet the specific needs of your molecule and your brand. Lonza now offers our new TiO2-free Swedish Orange-colored Capsugel® Enprotect® capsule for even more customization

With fewer manufacturing steps than alternative technologies on the market today, Lonza's enteric technology accelerates time to human and time to market

Our experts are here to help you at every stage

Define how we work together to fit your business needs

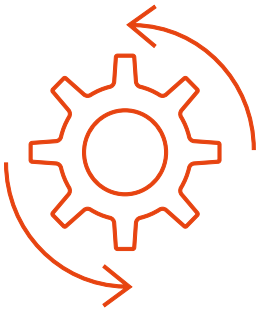
Partnering with us gives you access to our high-quality products and a bespoke range of services, enabling us to innovate together and address enteric delivery challenges.



Ready-to-use solution

Optimize your development process with our ready-to-use **Capsugel® Enprotect® capsule for enteric delivery release**

From concept to full scale manufacturing, we partner with you to provide high quality capsules to address patients' specific needs.



Bespoke solutions

Partner to help **solve delivery challenges** through capsule innovation

Leveraging Capsugel® Enprotect® capsule's bi-layered manufacturing technology, our Lonza Innovaform® Accelerator experts partner with you from concept to manufacturing, crafting tailored capsules that ensure formulation compatibility and meet your targeted release profile—advancing capsule innovation to support your pipeline goals.

Contact us

To speak to a capsule expert or request a sample of the Capsugel® Enprotect® capsule for enteric delivery, contact us or your Lonza Capsules & Health Ingredients sales representative

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