

DELASOL[®]
Delayed Release



DELASOL[®]

Enteric Capsule Release

- First of its kind
- Production with one gelatin product in one process
- Creates value-added market opportunities

GELITA

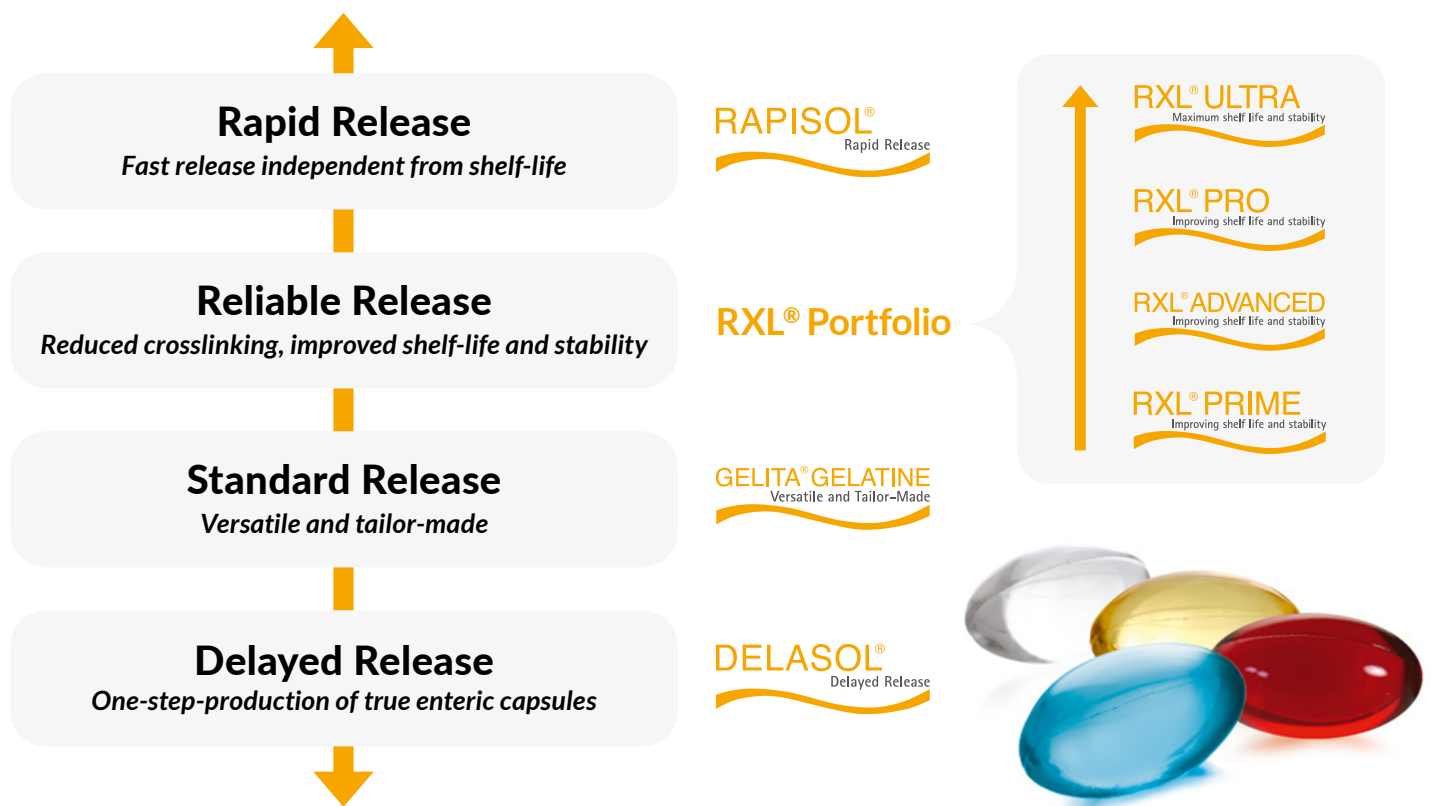
DELASOL®

A Unique Solution to Expand your Capsule Release Options

GELITA offers a comprehensive portfolio of gelatins that provides a broad release profile in soft capsules. Besides the variety of versatile and tailor-made standard gelatins, there is the RXL® Portfolio for improved capsule shelf-life and stability. These special gelatins provide reliable release and reduced crosslinking properties, even under extreme storage conditions. RAPISOL® is a softgel gelatin that enables fast fill release – not only for fresh capsules, but also during the shelf life. GELITA's portfolio of softgel specialties is complemented by EASYSEAL®, which improves softgel seams and prevents leakers.

At the opposite end of the release profile spectrum, GELITA also offers a unique solution: DELASOL® – a gelatin product for the one-step production of true enteric capsules.

Controlled Release Portfolio



DELASOL®

Managing Oxidation in Omega-3 Capsules

With consumers increasingly focusing on a healthy lifestyle, the popularity of health-promoting supplements is on the rise. A good example of this is omega-3 products, which are forecast to have annual growth rates of 13.8 percent by 2029*.

Maintaining full bioavailability

Omega-3 fatty acids are extremely sensitive to oxidation, which is why gelatin capsules are essential to protect the valuable oils. However, when capsules open in the stomach, the released fill is not protected against aggressive gastric acid that triggers oxidation of fatty acids. Enteric capsules are therefore necessary to transport the active ingredients intact into the intestine. Our customized gelatin product DELASOL® not only protects the valuable fatty acids from external influences during storage, but also from aggressive stomach acid. This preserves the high product quality and bioavailability until it reaches the intestine.

Save time and money with DELASOL®

Maintaining full bioavailability saves valuable ingredients, as no overdosing is necessary. Gelatin capsules with DELASOL® can also be produced in just one process step. This makes them a cost-effective alternative to classic enteric-coated capsules, which traditionally have to be produced in two steps.

* Markets & Markets, Table 50
(Omega-3 Market, by Application,
2024 - 2029)





Protecting sensitive fillings

Consumers have been ingesting nutrients in soft capsules for decades due to their ease of swallowing and convenience. However, sensitive fillings in particular often lose their desired effect if they are released in the stomach and not in the intestine. Another annoying problem that can occur when taking fish oil and other omega-3 fatty acids, for example, is a fishy burp and aftertaste.

With DELASOL[®], GELITA therefore offers the first commercially available gelatin product of its kind that enables the one-step production of enteric capsules that open in the intestine (instead of in the stomach, as is the case with conventional gelatin capsules).

Added Value with DELASOL[®]

Most enteric delivery systems are produced by applying an acid-insoluble coating to freshly produced soft capsules. This intensive two-step process adds time and money to the cost of each enteric capsule. Additionally, this coating produces an opaque shell – which is less desired by consumers.

With DELASOL[®], capsule producers now have the ability to create enteric capsules using existing equipment in a one-step process – avoiding additional time and costs – while creating brilliantly clear capsules.

Proven Enteric Release

DELASOL[®] allows manufacturers to produce enteric capsules that adhere to USP (US Pharmacopeia) and the Ph.Eur. (European Pharmacopeia) dissolution parameters.

THESE PARAMETERS INCLUDE:

- Capsules will not release more than 10% of the fill during two hours in 37°C simulated gastric fluid
- Capsules will be fully dissolved by 45 min in simulated intestinal fluid

Dissolution results with 20 oblong enteric fish oil capsules produced with DELASOL[®].

- 0% of capsules released the fill in simulated gastric acid (representing the stomach)
- 100% of the capsules showed NO RELEASE (no “leakers”)
- < 10 min = average time for capsules to open after pH adjustment to represent intestinal fluids

Dissolution results

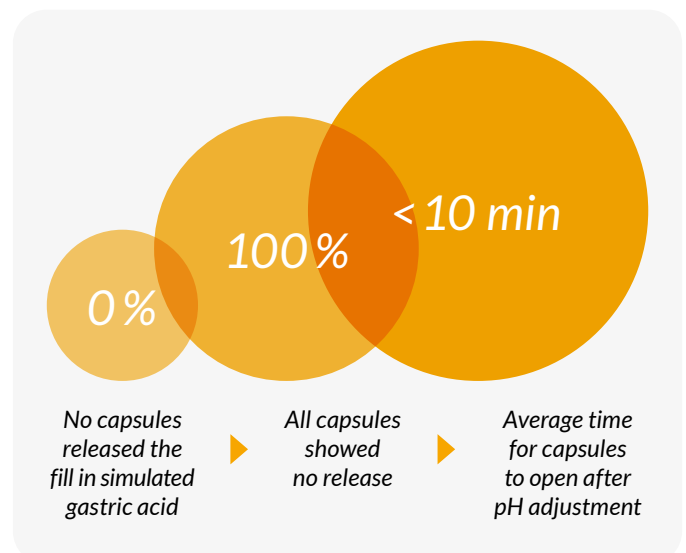


Figure 1: Gelatin Shell Dissolution – DELASOL® soft gelatin capsules compared to standard gelatin capsules

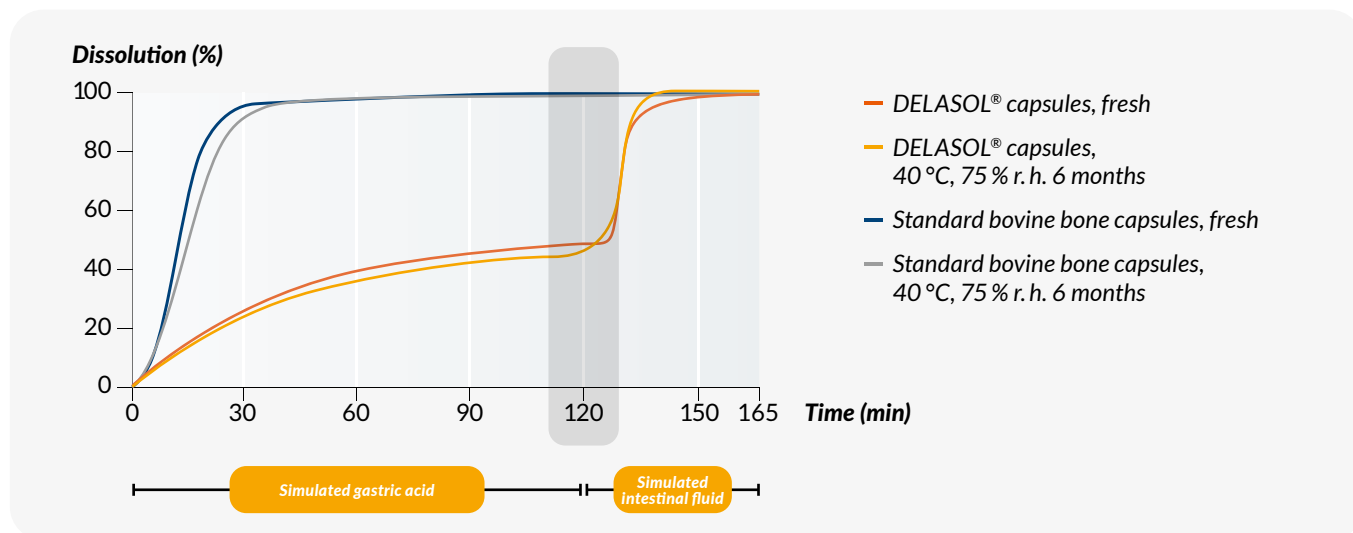


Table 1: Results of fill release for soft gelatin capsules made from DELASOL®

STORAGE CONDITIONS	No. Capsules released the fill in acid	No. Capsules passed acid stage	Average time for capsules to open after pH adjustment [min]	% Average gelatin dissolved after 2h in acid
FRESH	0/6	6/6	1.67	45.0
40°C, 75% R.H. CLOSED 3 MONTHS	0/6	6/6	1.65	47.5
40°C, 75% R.H. CLOSED 6 MONTHS	0/6	6/6	2.28	47.6

As figure 1 shows, the fresh gelatin capsules made from standard gelatin show a shell dissolution of 100% within 30 minutes. However, fresh capsules produced from DELASOL® provide a delayed dissolution of the shell. After 2 hours at pH 1.2 in simulated gastric fluid, only 45% of the gelatin shell was dissolved (table 1). After adjusting the pH from 1.2 to 6.8 the DELASOL® capsules start to dissolve. Within 30 min the soft gelatin capsules are completely gone in tribasic sodium phosphate solution.

After 6 month accelerated aging at 40°C, 75% r. h. (closed) capsules from standard gelatin show some delay in shell dissolution. The DELASOL® capsules provide similar dissolution kinetics as fresh capsules. Neither a delay in capsules dissolution nor an increased dissolution is visible and the oil release is similar after storage. These results prove that DELASOL® provides true enteric behavior also under accelerated ICH aging conditions.



One Product. One Step.



DELASOL® Add Value to Consumers and Industry

BENEFITS OF DELASOL®

- Prevents harm of sensitive fill ingredients by the acidic environment of the stomach.
- Promotes consumer convenience by eliminating fishy burps often associated with fish oils.
- Offers true enteric performance.
- Reduces additional time and processing steps associated with traditional enteric coating processes.
- Provides an enteric solution with one product and one process.

PRODUCT CHARACTERIZATION

- Product appears as faint yellow to amber granules or powder and is readily soluble in warm water.
- Produced in accordance with FDA regulations, HACCP, ISO9001: 2015 and FSSC22000.
- Product is suitable for products for Health & Nutrition, Over-the-counter (OTC) and pharmaceutical applications.

DELASOL® Gelatin

Type, Pharmaceutical Grade

RAW MATERIAL	Name of gelatin	Bloom [g]	Viscosity 6.67%/60°C [mPas]
BOVINE BONE	DELASOL® 130 Bloom Bovine Bone Gelatin Product	115 - 145	6.0 - 12.0

GPI provides knowledge and support

GELITA Pharma Institute (GPI) provides selected and tested formulations and is ready to support development activities with its expertise.



DELASOL® is protected by IP

- U.S. Patent 10,238,603.
- Europe: 3 191 083
- Brazil: BR 11 2017 003135-3
- China: ZL201580048106.1
- India: 344251
- South Korea: 10-2305346

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