

GELITA® EC

Enteric Capsule Release



Enteric Capsule Release GELITA® EC



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

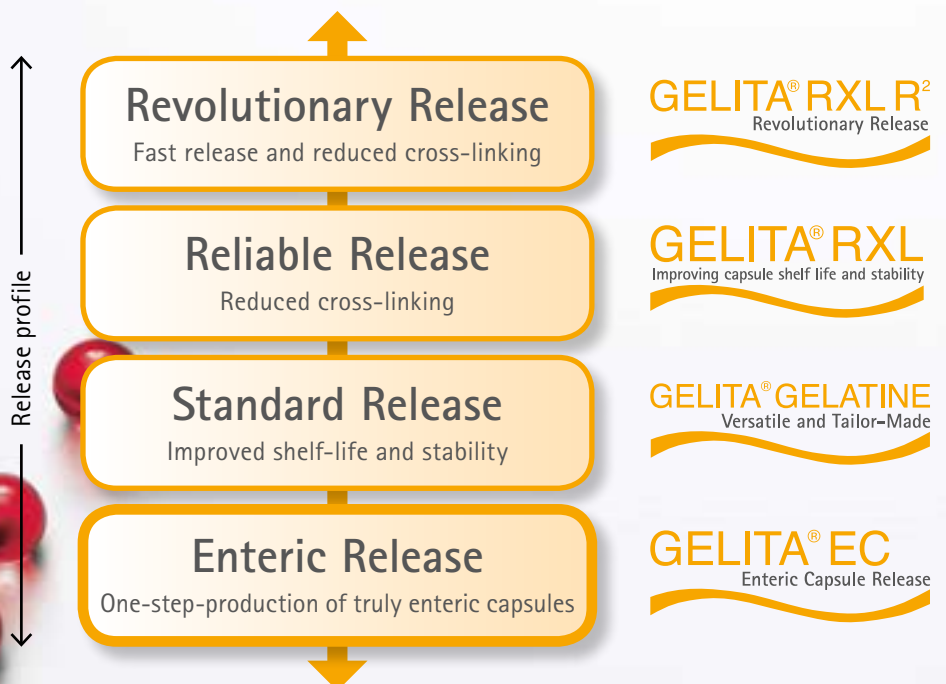
GELITA® EC

Expanding GELITA's Portfolio of Capsule Release Possibilities

GELITA offers a comprehensive portfolio of gelatines that provides a broad release profile in soft capsules. Besides variety of versatile and tailor-made standard gelatines, there are GELITA® RXL and GELITA® RXL Advanced for improved capsule shelf-life and stability. These special gelatines provide reliable release and reduced cross-linking properties, even under extreme storage conditions. This GELITA capsule gelatine portfolio is complemented by GELITA® RXLR² for revolutionary fill release. The soft capsules produced with GELITA® RXLR² offer faster release of the fill and offer the added advantage of the reduced cross-linking properties of the RXL technology.

And, now – on the opposite end of the release profile spectrum, GELITA offers GELITA® EC; a gelatine product for the one-step production of truly enteric capsules.

Release Profile of the GELITA® Portfolio



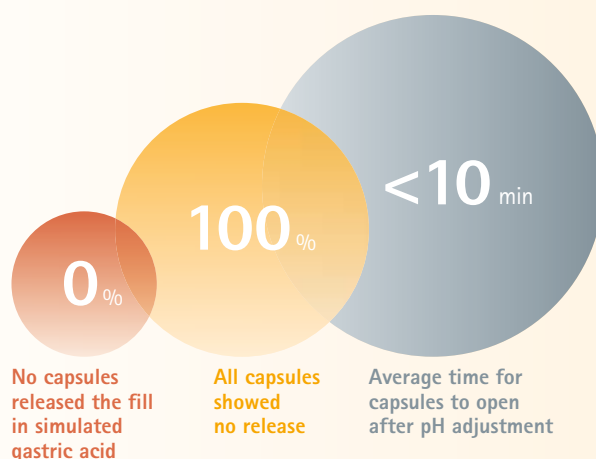
GELITA® EC

The perfect (dis)solution





Dissolution results



! Satisfying Consumer Demand

Consumers have been ingesting nutrients in soft capsules for decades due to their easy of swallowing and convenience. However, one nagging issue has been plaguing consumers for as long as they've been ingesting fish oil and other omega-3 fatty acids: fishy burps and aftertastes. This undesirable effect has even demotivated the otherwise health conscious consumers to avoid taking fish oil supplements altogether.

Until now. GELITA® EC – the first commercially available gelatine product of its kind – allows for the one-step production of enteric capsules that open in the intestine (instead of the stomach, as with traditional gelatine capsules).

! Added Value with GELITA® EC

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 GELITA® EC, capsules 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

GELITA® EC 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 GELITA® EC.

- 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



Figure 1: Gelatine Shell Dissolution – GELITA® EC soft gelatine capsules compared to standard gelatine capsules

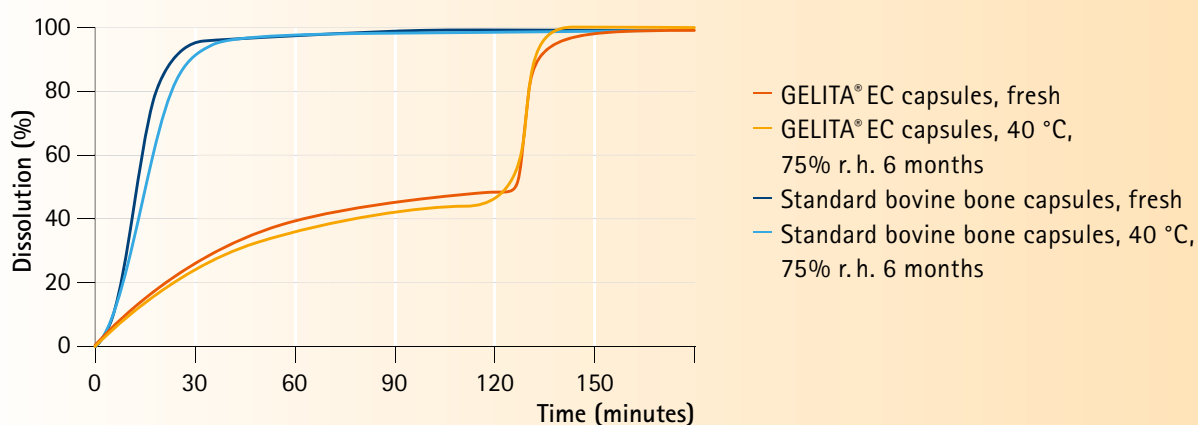


Table 1: Results of fill release for soft gelatine capsules made from GELITA® EC

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

After 6 month accelerated aging at 40 °C, 75% r. h. (closed) capsules from standard gelatine show some delay in shell dissolution. The GELITA® EC 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 GELITA® EC provides true enteric behavior also under accelerated ICH aging conditions.

One Product. One Step.

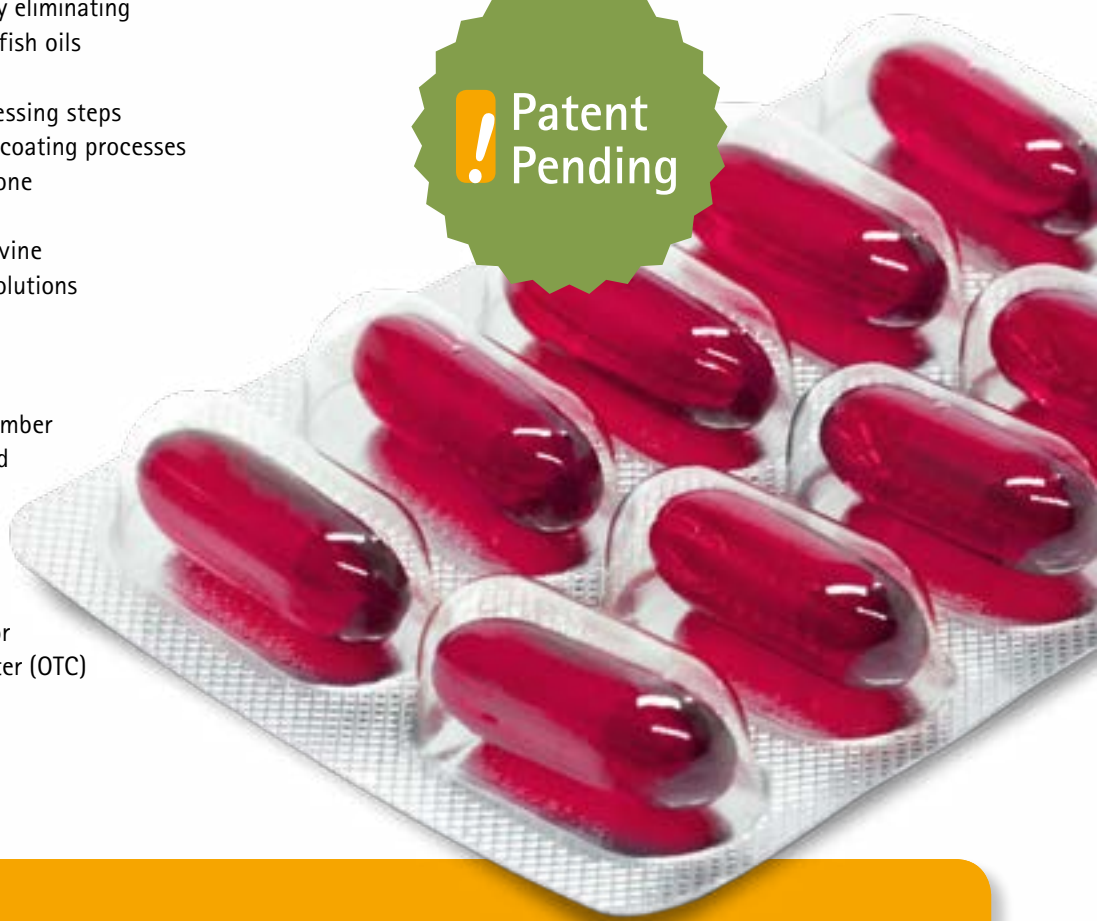
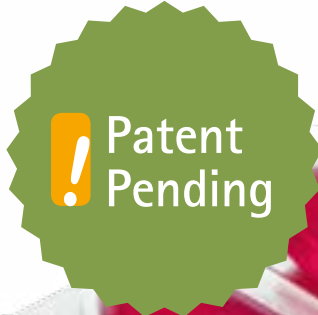
GELITA® EC Add Value to Consumers and Industry

Benefits of GELITA® EC

- 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
- Although currently available in bovine bone types, GELITA is developing solutions from other raw material sources.

Product characterization

- Product appears faintly yellow to amber granules or powder and is provided 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.



GELITA® EC

RAW MATERIAL	NAME OF GELATINE	BLOOM [g]	VISCOSITY 6.67 %/60 °C [mPas]
Bovine Bone	GELITA® EC 130 Bloom Bovine Bone Gelatine Product	115 – 145	6.0 – 12.0

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