



EASYSEAL®

Reliable Softgel Seams

- Significant reduction of leakers
- Higher machine speeds
- Reduced production costs

GELITA

EASYSEAL®

The easy solution to get rid of leakers

Optimize your entire soft capsule production just by changing one parameter – the gelatin. By using GELITA's new solution EASYSEAL®, you can minimize issues with leaking softgels. EASYSEAL® is an innovative pharmaceutical grade gelatin appropriate for all products that require special care or even special equipment (double step die toolings) or only work at lower machine speeds. Our new solution leads to a significant reduction of leakers and allows the enhancement of product quality while reducing production time and costs.

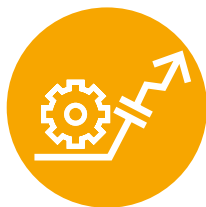


GPI provides knowledge and support

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



Leaking softgels – a multifactorial problem



During the encapsulation process and following drying step in the production of soft capsules, not fully sealed capsules can appear, causing so called “leakers”. The main cause of this effect can be difficult to identify because many different parameters can influence the seam quality during the encapsulation process. To reduce the scrap rate caused by weak or incomplete seams, many manufacturers restrict their machine speeds which leads to poor equipment effectiveness.

Worst case: leakers ruin the batch



Just exchange the gelatin



GELITA has extensively investigated the issue and found that the choice of gelatin has a significant influence on the occurrence of leakers. Based on extensive testing, we have developed a new, innovative gelatin grade that enables the production of leaker-free capsules even at high machine speeds. With EASYSEAL®, we offer a highly processable gelatin that optimizes seam forming and enhances seam thickness and stability in soft capsule systems (shell and fill). As a result, the capsules are more resistant against physical stress.

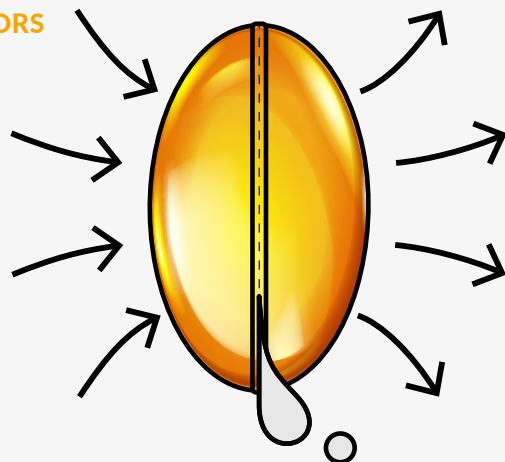
The easy solution: EASYSEAL® from GELITA



Influencing factors and negative effects of leakers

INFLUENCING FACTORS

- Fill
- Rotary die tool
- Machine speed
- Temperature settings
- Gelatin
- Colors in the shell, especially pigments



NEGATIVE EFFECTS

- Decreased yield
- Decreased productivity
- Limited productivity optimization
- Contamination of surrounding capsules
- Limitation of shell coloration
- Negative effect on coating
- Negative effect on capsule taste
- Changed API dose and/or irritation of oral mucosa
- Waste of expensive fills



Optimize seam thickness – as well as machine speeds

It is well known that faster machine speeds lead to thinner capsule seams which are less robust. With EASYSEAL®, the seam thickness can be significantly enhanced – typically above 50 % for the bovine gelatin and above 40 % for the porcine version – by using default settings on a standard softgel machine. The seams show extremely homogeneous shape (figure 1) and are nearly as thick as the capsule walls. This allows the production of high-quality, leaker-free capsules, with higher Burst-Strength (figure 2), produced with higher machine speeds with only minor changes of process settings and without changing the machine design (figure 3). With EASYSEAL®, the process is more robust and various process optimizations and cost reduction are possible.

Figure 2: Burst-Strength of capsules with standard gelatin versus EASYSEAL®

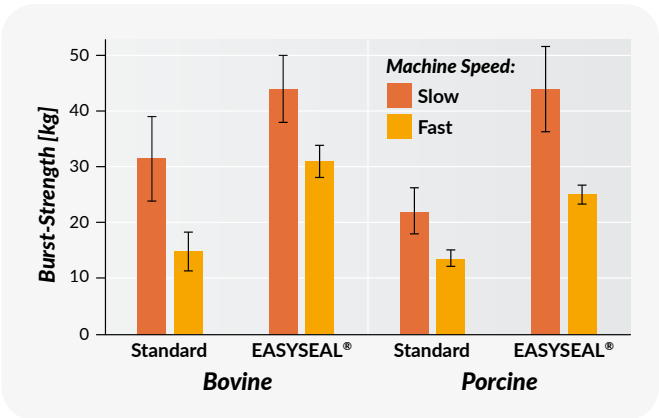


Figure 3: EASYSEAL® – thick and robust capsule seams

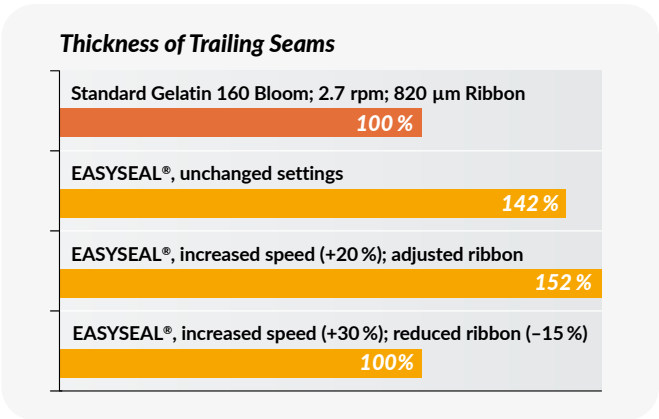
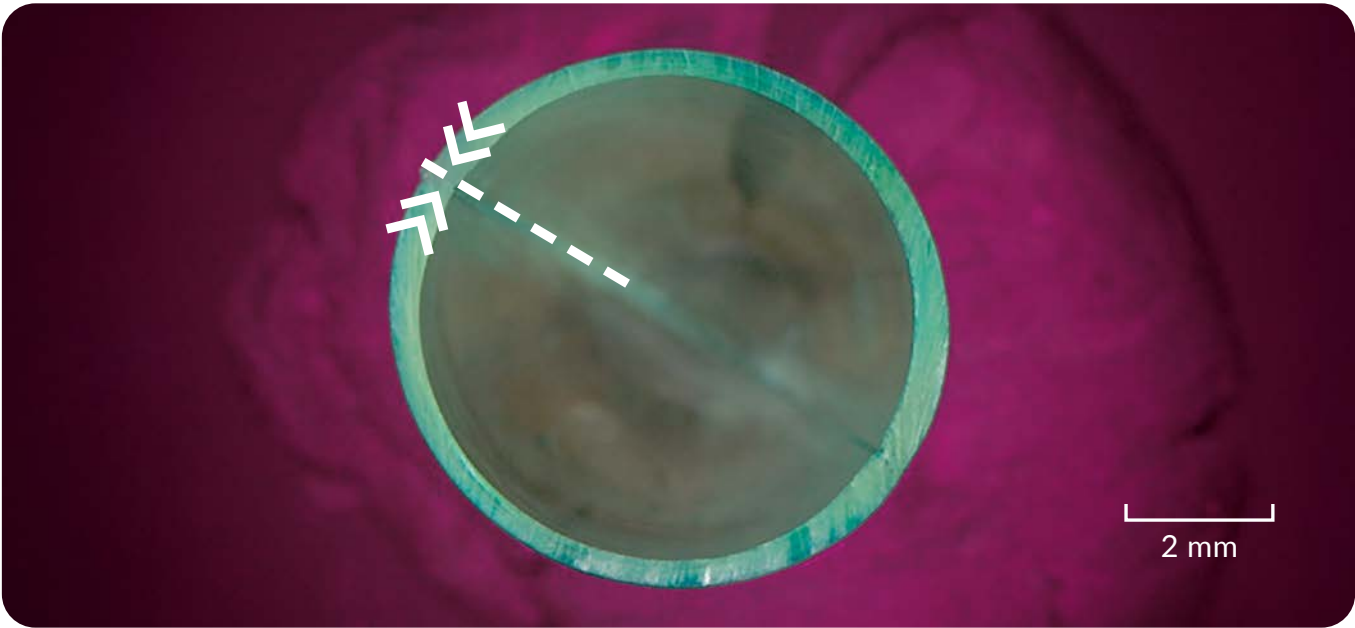


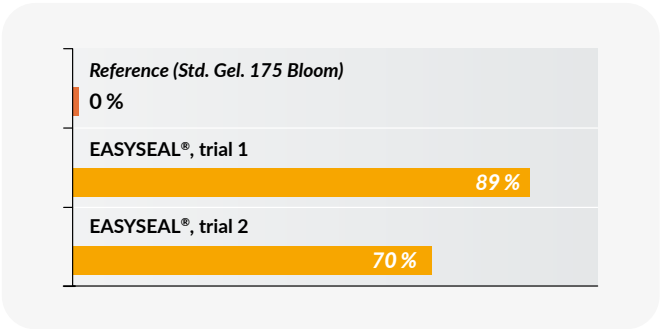
Figure 1: Cross-section of a soft capsule with EASYSEAL® (microscope image)



EASYSEAL® – Reduced rate of leakers

The reference product was produced with a standard 175 Bloom gelatin and a soy lecithin fill. The capsules were dried with continuous tumble drying until the desired hardness was achieved. The reference product was found to have leaking capsules in all tumblers, the batch was considered a failure. Trials were then performed with the EASYSEAL® gelatin, while keeping all other encapsulation parameters the same. One trial resulted in 8 out of 9 tumblers possessing the absence of leaking capsules, while in a second trial, 7 out of 10 tumblers had no leaking capsules (figure 4). This significantly lowered production costs, as those tumblers without leakers don't need to be sorted.

Figure 4: Passing tumblers without Leakers



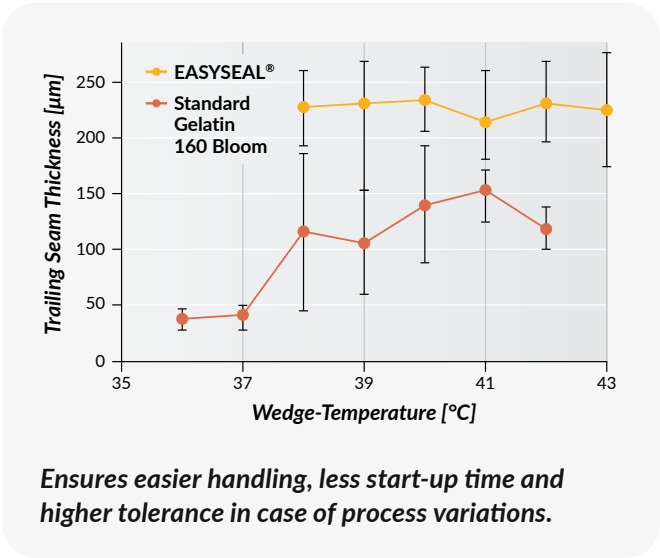
Faster Drying

Because of new product performance, less water is required in the gellmass (figure 5) and evaporation of water is improved. Both effects result in only 18 hours of drying time, compared to 32 hours drying time of Standard product → about 50 % faster drying.

Figure 5: Gellmass compositions

	Reference	EASYSEAL®
GELATIN	44	52
GLYCEROL	22	20
WATER	34	28

Figure 6: Constantly high seam thickness over a wide temperature range on the wedge



Temperature-independency

With EASYSEAL® the seam formation capability is much less dependent on the wedge temperature than with standard gelatin (figure 6). This means that variations in the gel mass cooking or aging times have much smaller impact on the encapsulation process while process robustness is significantly increased.

EASYSEAL® allows product-, process- and cost-optimization, according to your specific process requirement and fill material:

- Higher Seam Thickness → reduction of leakers and enables encapsulation of ingredients that would otherwise not be able to be processed (e.g. emulsions)
- Reduced leaker → higher yield of products in spec, less cross-contamination of capsule batches and less fill wasted
- Reduced ribbon thickness, higher machine speed and reduced drying time → same quantity and quality of capsules (compared with Standard Gelatin) at reduced costs

Exemplary results from pilot trials with various formulations and conditions on three different industrial scale equipments



One solution. Many issues resolved.

BENEFITS OF EASYSEAL®

- Reduced rate of leaking soft capsules at standard machine speed
- Higher capsule output in same production time
- No need to sort out leaking capsules or to clean the capsule batch
- More robust production due to higher tolerance for process parameters
- Lower maintenance by staff during production
- Cost-saving due to less leakers (especially for expensive APIs/fills)
- Allows products that can't be produced efficiently today due to leakers – e.g. Softgels with Lecithin

PATENT PENDING

Product characterization

- Produced in accordance with FDA regulations, HACCP, ISO9001:2015 and FSSC22000
- Product is suitable for products for Health & Nutrition and pharmaceutical applications – Rx as well as Over-The-Counter (OTC).
- China Drug Master File (CDMF) registration available for selected types.

EASYSEAL® Gelatin Types, Pharmaceutical Grade

RAW MATERIAL	Name of gelatin	Bloom [g]	Viscosity 6.67%/60 °C [mPas]
BOVINE BONE	EASYSEAL® 220 Bloom Limed Bovine Bone Gelatin	176 – 264	1.7 – 2.5
	EASYSEAL® 200 Bloom Limed Bovine Bone Gelatin	160 – 240	1.7 – 2.5
PORCINE SKIN	EASYSEAL® 200 Bloom Porcine Skin Gelatin	160 – 240	1.5 – 2.3

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