



## GELITA<sup>®</sup> Pharmaceutical Gelatine – Standard for the Industry

- Excellent film forming properties
- Thermo-reversible gelling
- Excellent emulsifying and dispersing properties
- Best adhesive behavior
- Excellent protection of ingredients



# GELITA<sup>®</sup> Pharmaceutical Gelatine

## A Multitalented Excipient for Pharmaceutical Applications

For many pharmaceutical applications, GELITA<sup>®</sup> Gelatine is indispensable for decades. Although mostly used for hard and soft capsules, GELITA<sup>®</sup> Pharmaceutical Gelatine is also essential for many other applications. It's a binder in tablets and acts as matrix in vitamin coating. Low endotoxin gelatines are the basis for plasma expanders, vaccines and haemostatic sponges.

In particular, it's the film forming ability, thermo-reversible gelation properties and adhesive behavior that make GELITA<sup>®</sup> Gelatine so versatile. With outstanding innovations such as the patented GELITA<sup>®</sup> RXL gelatines for reduced cross-linking, GELITA has set new standards in stability and dissolution for gelatine capsules. As a leading supplier of all types of gelatine, GELITA offers also Kosher and Halal variants.



### **Hard Capsules** Protection and Bioavailability

Hard gelatine capsules are the dosage form of choice for medicines and food supplements. They are ideal for powdered and granulated products. GELITA® Hard Capsule Gelatine offers optimal setting properties and improved gliding characteristics. GELITA® Pharmaceutical Gelatine is considered as food and provides fast machinability, ideal dissolution properties and an optimal protection of fill ingredients. High Bloom gelatine (between 200 and 260 g Bloom) is the best choice for the production of hard gelatine capsules. The capsule shell can be designed in such a way that the release of the active substance can be controlled and the bioavailability increased. Controlled release of the active substance can be achieved by coating the capsules.

- Ideal for powder and granulate fillings
- Protection of the fill from atmospheric oxygen, light, moisture and dust
- Optimal setting properties & fast machinability
- Optimized dissolution properties
- Specialties: Hard capsule gelatine with improved gliding properties

Soft capsules are easy to swallow.



### **Soft Capsules** Easy Swallowing

Soft gelatine capsules are readily accepted by consumers. They are easy to swallow and neutral in taste. Perfectly suited for liquid or semi-solid fillings, soft capsules are widely used to deliver pharmaceutical substances and a wide range of nutraceutical supplements, such as omega-3 fish oils. GELITA® Soft Capsule Gelatine is available from various raw materials and offers optimized dissolution performance hence improved bioavailability of the active ingredients. For critical fillings our innovative GELITA® RXL and GELITA® RXL R<sup>2</sup> portfolio provides solutions with regard to reduced cross-linking properties and controlled fill release. In general medium Bloom gelatine (between 150 and 200 g Bloom) is used for the production of soft gelatine capsules. Special coatings enable gastric juice-resistant capsules for a delayed dissolution in the intestine.

- Perfect for liquid or semi-solid fillings
- Protection of sensitive fills from atmospheric oxygen, light, moisture, dust and other environmental influences
- Optimized dissolution – improved bioavailability
- Optimal setting properties
- Specialties: GELITA® RXL and GELITA® RXL R<sup>2</sup> portfolio with reduced cross-linking properties and revolutionary fill release



### Vitamin Coating Protection and Dispersibility

Oil-based vitamins such as vitamin A or E, carotinoids and poly-unsaturated fatty acids have special requirements: they are poorly dispersible in water and are extremely light and oxygen sensitive. In these applications, gelatine can play a key role as a multifunctional agent and acts as a perfect matrix material with protective and emulsifying properties for the actives. GELITA® Pharmaceutical Gelatine provides ideal functionality to generate a free-flowing powder from oily substances. Low Bloom porcine skin and bovine hide split gelatines (between 100 and 140 g Bloom) are used for this application.

- Embedding of oil-based substances into gelatine generates a free flowing powder.
- Gelatine as multifunctional agent
- Perfect matrix material - optimal flow properties - ideal further processing (e.g. tablet pressing, fill into hard capsules)

### Vaccines Stabilization of Life Savers

Vaccines save lives. The collagen peptides VACCIPRO® have been designed to stabilize vaccines and thereby contribute to safe and effective vaccination. With a very low allergenic potential, high bioavailability and excellent cell tissue affinity, VACCIPRO® has been described as the "gold standard" by a number of leading vaccine manufacturers.

- For vaccines stabilization
- Low endotoxin levels
- Low allergenic potential
- Collagen peptides with a defined molecular weight



Turn vitamins into a free flowing powder.



Vaccines may deliver disease immunity.





## Innovative Medical Devices Gentle with the Body

For tissue scaffolds, ocular implants, bone fillers or even surgical sealants and wound healing devices, GELITA offers highly specialized medical gelatins. MedellaPro® has been used by the world's leading manufacturers for many years to develop and produce cutting-edge medical devices. MedellaPro® replaces human tissue grafts – the perfect and less invasive alternative to autografts directly from the patient or other sources. This not only reduces costs and risks, but also increases patient comfort.

MedellaPro® meets all the requirements of the world's top pharmacopeial entities, offering exceptionally high levels of purity, low allergenic potential, high tolerance by the body, low bioburden and an affinity for tissue cells. Our collaboration with numerous regulatory entities helps our customers to develop cutting edge products, as well as achieving the required regulatory product approvals.

- For cutting edge medical devices
- Low endotoxin levels
- Low allergenic potential
- A gelatine ideal for use in wound healing devices, bone pastes and surgical adhesives.

Highly specialized gelatine for ocular implants.



Tablets are the most popular delivery form.



## Tablets, Suppositories, Pastes Adhesive Binder for Stability

Tablets are one of the most popular oral solid dosage forms for pharmaceuticals and nutraceuticals. In the production of tablets, sugar-coated tablets, in the formulation of suppositories and for the production of zinc paste dressings, gelatine and collagen peptides act as natural adhesive binders and improve the stability of the final product. GELITA® Pharmaceutical Gelatine provides unique film forming ability, thermo-reversible gelation properties and optimal adhesive behavior for production of tablets and sugar-coated tablets. In wet granulation, a medium-Bloom aqueous solution of bovine hide split, bone or porcine skin gelatine (about 180g Bloom) is used as binding agent.

- Binder in tablets for increased stability
- Unique film forming ability
- Thermo-reversible gelation properties
- Optimal adhesive behavior



### Blood Plasma Expanders Excellent Compatibility, no Accumulation in the Organs

Blood plasma expanders based on GELITA® Pharmaceutical Gelatine are used to enhance the remaining circulating blood in emergency situations. Very special types of gelatine – those that conform to the most stringent requirements and which are subsequently modified by the pharmaceutical industry – are used for plasma expanders. Plasma expanders based on gelatine are ideal since they exhibit excellent compatibility with the body. In contrast to dextrans and hydroxyethyl-starches that can frequently be detected in the body for many days, gelatine does not tend to accumulate in organs. A fact that makes it an ideal basis for safe and compliant emergency medicine. High Bloom bone gelatine (220 to 270 g Bloom) is used for this purpose. Plasma expanders usually contain 3.5 to 5.5% gelatine along with the necessary electrolytes in the form of calcium, sodium and chloride ions.

- Low endotoxin gelatine provides excellent compatibility with the body.
- More compatible to the human body than dextrans and hydroxyethyl-starches.

Blood plasma expanders based on GELITA® Gelatine do not accumulate in the body.



Haemostatic sponges stop bleeding and enhance healing process.



### Haemostatic Sponges Stop Bleeding and Disappear

Haemostatic sponges, also frequently used in dental medicine, are virtually indispensable in hospital surgeries. Gelatine sponges can stop bleeding reliably and enhance the healing process. Sponges made from GELITA® Pharmaceutical Gelatine are completely resorbed by the body during the wound-healing process and no removal of the sponge and therefore reopening of the wound is necessary. GELITA® Pharmaceutical Gelatine can be also used for sponges spiked with APIs (active pharmaceutical ingredients). High Bloom bovine hide split and porcine skin gelatins (> 240 g Bloom) are used for sponges.

- Stop bleeding and are completely resorbed by the body.
- GELITA low endotoxin gelatine provides excellent compatibility with the body.

### **Quality and Safety** Strictest Quality Controls

Gelatine is a safe product, produced from native collagen occurring in the skin and bones of animals. GELITA® Pharmaceutical Gelatine is produced using the highest possible production standard and under the most stringent hygienic requirements. The complete traceability and safety of gelatine and its raw materials are guaranteed by comprehensive controls from the supply of the raw materials to the final product. GELITA® Pharmaceutical gelatine is tested according to the current official pharmacopoeias as well as special often even more strict customer requirements. The certificated GELITA Quality Management System in accordance with international standards such as ISO 9001, 14001, 50001 and FSSC 22000 guarantees worldwide consistent high quality and safety during the production process. Certificates of Suitability (CoS) are available for GELITA Pharmaceutical Gelatine of bovine origin. On request Kosher and Halal certificates are available. GELITA® Pharmaceutical Gelatine is a versatile excipient in pharmaceutical technological applications. Its advantages are based on its natural combination of film- and gel-forming properties. GELITA® Pharmaceutical Gelatine is neutral in taste and odor, is practically non-allergenic and is completely absorbed by the body.

- Manufacturing complies to the highest production standards
- Certificated Quality Management System: ISO 9001, 14001, 50001 and FSSC 22000
- Kosher and Halal certificates are available
- Certificates of Suitability for bovine gelatins
- Tested according the current pharmacopoeias

### **Technical Support** There Where You Need It

At GELITA, you don't just buy high quality pharmaceutical gelatine that are specifically tailored to you application, you also get a comprehensive and unparalleled service package. We offer professional advice, product development and formulation support, process enhancement and guidance in regulatory affairs and marketing. And if that wasn't enough, there's our scientific backing and our remote and on-site technical service.

- Team of notable experts to support customers
- Service on site
- Formulation and development support
- Regulatory guidance

At GELITA technical support is always part of the deal.





## GELITA® Pharmaceutical Gelatine – Indispensable for Many Pharmaceutical Applications

- Hard Capsules – protection and improved bioavailability
- Soft Capsules – easy swallowing and protection
- Vitamin Coating – protection and dispersibility
- Vaccines – stabilization of life savers
- Innovative Medical Devices – gentle with the body
- Tablets, Suppositories, Pastes – adhesive binder for stability
- Blood Plasma Expanders – excellent compatibility, no accumulation in the organs
- Haemostatic Sponges – stop bleeding and disappear

GELITA  
provides 

- Tailormade solutions
- Highest quality and safety standards
- Formulation and development support
- Regulatory guidance



# Realize essential and advanced pharmaceutical products with added value!

GELITA® Pharmaceutical Gelatine can enhance the most diverse pharmaceutical applications, including medicines, vitamin coating, tablets, vaccines, suppositories, pastes, blood plasma expanders and haemostats.

Gelita excludes any warranty and/or liability for any and all claims arising from or in relation with statements made in this brochure and/or the positioning of GELITA® Pharmaceutical Gelatine, including but not limited to claims based on misleading advertising and/or breach of relevant German and EU legislation. The positioning as well as the packaging, labelling and advertising of the client's products with GELITA® Pharmaceutical Gelatine falls solely within the responsibility of the client.

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**GELITA**  
Improving Quality of Life