



Endotoxin Controlled Excipients

Pioneering bioscience applications

- High biocompatibility and biodegradability by nature
- Versatility
- Safe use in food and pharmaceutical products
- Traceability (ISO22442)
- Batch-to-batch consistency

VACCIPRO®
Advanced Stabilization



VACCIPRO®

Advanced Vaccine Stabilization

Vaccines save lives. The collagen peptides VACCIPRO® have a long history of use in vaccine stabilization and thereby contribute to safe and effective vaccination. VACCIPRO® has been described as the “gold standard” by a number of leading vaccine manufacturers. Vaccines stabilized with VACCIPRO® show very low allergenic potential, high bioavailability and excellent cell tissue affinity.

VACCIPRO® is ideal for stabilizing sensitive vaccines

The choice of stabilizing agents plays a pivotal role in maintaining the efficacy and integrity of vaccines. VACCIPRO® boasts outstanding biocompatibility by nature, rendering it safe for use in vaccine formulations. Its biodegradable nature aligns with the principles of sustainability and safety, as it undergoes enzymatic degradation into biologically harmless byproducts within the body. For lyophilized vaccines GELITA provides hydrolisates with a special molecular weight distribution.

- Collagen peptides with a defined molecular weight
- For vaccine stabilization
- Efficient moisture control during the lyophilization process
- Ensuring potency and efficacy of vaccine agents over extended storage periods
- Controlled endotoxin levels
- Low allergenic potential



GELITA's Endotoxin Controlled Excipients*

Overcoming the endotoxin challenge

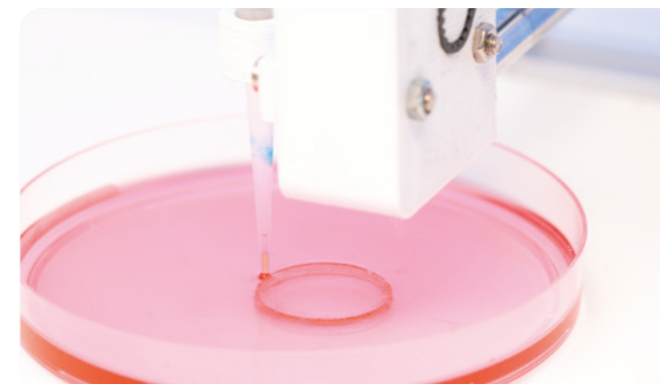
Gelatin and the related collagen peptides belong to the most versatile excipients used in bioscience. But as standard pharmaceutical grade gelatin naturally contains endotoxins that can cause severe problems in several applications, their detection and removal are crucial in pharmaceuticals, medical devices, and healthcare settings to ensure product safety and patient well-being.

With our endotoxin-controlled grades MEDELLAPRO® and VACCIPRO®, GELITA provides highly specialized gelatins and collagen peptides for various bioscience applications – offering exceptionally high levels of purity, low allergenic potential, high tolerance by the body, low bioburden and an affinity for tissue cells.

KEY APPLICATIONS

for endotoxin-controlled gelatins

- **Biological Assays:** Minimizing endotoxin contamination is essential for obtaining reliable data from experiments
- **Animal Studies:** Controlling endotoxin levels is crucial for accurately assessing the effects of experimental interventions and ensuring the welfare of research animals
- **Medical Devices and Implants:** Low endotoxin levels are essential to minimize the risk of triggering spontaneous immune response and complications
- **Clinical Research and Drug Development:** Ensuring low endotoxin levels in pharmaceutical formulations and medical products is critical for obtaining regulatory approval and ensuring patient safety
- **Patient Care and Treatment:** Controlling endotoxin levels is essential for preventing endotoxemia, septic shock, and other life-threatening complications associated with endotoxin exposure



MEDELLAPRO®
For Innovative Bioscience



MEDELLAPRO®

Life Science Applications

For tissue scaffolds, ocular implants, bone fillers or even surgical sealants and wound healing devices, GELITA offers highly specialized pharmaceutical grade gelatins. MEDELLAPRO® has been used by the world's leading manufacturers for many years to develop and produce cutting-edge medical devices.

For instance products containing MEDELLAPRO® can replace 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.

HEMOSTATIC AGENTS

GELITA's MEDELLAPRO® is very often used as base for hemostatic agents used in surgical procedures and trauma care. They promote blood clotting by adhering to the wound site and accelerating the coagulation process.

WOUND CARE

Our gelatin hydrogels have been employed as wound dressings due to their ability to maintain a moist environment conducive to wound healing. These dressings provide a scaffold for cell proliferation and tissue regeneration while protecting the wound from external contaminants.

BLOOD PLASMA EXPANDER

Due to its excellent natural compatibility with the body, MEDELLAPRO® gelatin is an ideal basis to produce expanders for safe and compliant enhancement of the remaining circulating blood in emergency situations.

EMBOLIZATION

Gelatin micro- and submicron particles have been widely used as embolic agents and drug delivery carriers, respectively. Gelatin microparticles can be used as a temporary embolic agent.

DRUG DELIVERY SYSTEMS

GELITA's MEDELLAPRO® gelatin is the perfect carrier for the controlled and targeted release of therapeutic agents.

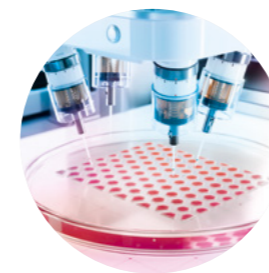
DIAGNOSTIC IMAGING

Gelatin-based hydrogels with MEDELLAPRO® can be used in contrast agents for diagnostic imaging modalities such as magnetic resonance imaging (MRI) and ultrasound.

MEDELLAPRO®

3D Bioprinting and Cell Culturing

MEDELLAPRO® emerges as the quintessential biomaterial for 3D bioprinting and cell culturing in human tissue engineering. Its unparalleled biocompatibility by nature, tailorable mechanical properties, printability, and biodegradability make it indispensable for fabricating functional tissue scaffolds with remarkable precision and efficacy.



TISSUE ENGINEERING VIA 3D PRINTING

Gelatin-based hydrogels and scaffolds are extensively used in tissue engineering to mimic the extracellular matrix (ECM) and support cell adhesion, proliferation, and differentiation. Gelatin scaffolds can be tailored to mimic specific tissue characteristics and promote the regeneration of various tissues such as bone, cartilage, and skin.



CELL CULTURE SUBSTRATES

Gelatin-coated surfaces are ideal as cell culture substrates to promote cell adhesion and proliferation in vitro. Gelatin coatings facilitate the adhesion of cells to culture dishes or scaffolds and provide a favorable environment for cell growth and experimentation in areas such as cell biology, drug screening and tissue engineering.



CELL CULTURED MEAT

Cell cultured meat is artificial meat obtained by culturing animal-derived cells in vitro. It is seen as a sustainable alternative to traditional meat production. Our MEDELLAPRO® gelatin facilitates cell-cultured meat production because it is safe, edible, and has many integrin-binding sites, which improve cell adhesion.

The GELITA ECE portfolio *at a glance*

GELATIN

Product Name	Animal/ Process	Country of Origin	DMF available	VIS (ISO22442)	Endotoxin level [EU/g]	Bloom [g]
MEDELLAPRO® 100 P 250	PS	USA	Y	Y	≤100	250
MEDELLAPRO® 100 P 275	PS	USA	Y	Y	≤100	275
MEDELLAPRO® 200 B 250	LBB	Europe	N	EDQM	≤200	250
MEDELLAPRO® 350 P 300	PS	Europe	N	Y ¹	≤350	300
MEDELLAPRO® 600 P 200	PS	USA	Y	Y	≤600	200
MEDELLAPRO® 600 P 250	PS	USA	Y	Y	≤600	250
MEDELLAPRO® 600 P 275	PS	USA	Y	Y	≤600	275
MEDELLAPRO® 800 B 275	LBB	Europe	N	EDQM	≤800	275
MEDELLAPRO® 1000 P 250	PS	Europe	N	Y ¹	≤1000	290
MEDELLAPRO® 1500 P 100	PS	USA	Y	Y	≤1500	100
MEDELLAPRO® 1500 P 200	PS	USA	Y	Y	≤1500	200
MEDELLAPRO® 1500 P 275	PS	USA	Y	Y	≤1500	275
MEDELLAPRO® 3000 P 240	PS	Europe	N	Y	≤3000	240

COLLAGEN PEPTIDE

Product Name	Animal/ Process	Country of Origin	DMF available	VIS (ISO22442)	Endotoxin level [EU/g]	MWD [kDa]
VACCIPRO® 2000 P	PS	USA	Y	Y	≤2000	2.5
VACCIPRO® B HMW	BH	Brazil	N	EDQM	-	12.0
VACCIPRO® P HMW	PS	Europe	N	Y ¹	-	12.0

DMF: Drug Master File PS: Pork Skin LBB: Limed Bovine Bone BH: Bovine Hide VIS: Virus Inhibition Study ¹ bridging study and animal tissue assessment available
EDQM: European Directorate for the Quality of Medicines & HealthCare

* GELITA AG as the leading manufacturer of gelatine including gelatine hydrolysate and collagen for edible, pharmaceutical and cosmetic applications.
MEDELLAPRO® and VACCIPRO® are produced in accordance with ISO 9001:2015 ; FSSC 22000 and corresponding EU or FDA food regulations, therefore those grades are declared as "fit for human consumption". Further as medical grade gelatines MEDELLAPRO® and VACCIPRO® are in compliance with the current version of Gelatin Monograph of Ph. Eur. and USP.

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