quali-pure
ADVANCING MEDICAL SCIENCE

QUALI-PURE™ GELATINS: WHERE PERFORMANCE MEETS REGULATORY COMPLIANCE

May 2024

Enhanced scrutiny of safety documentation

All medical devices placed on the EU market must be in conformity with the new Medical Device Regulation (EU) 2017/745 (MDR).

Rousselot's biomedical gelatins are developed to fully support Medical Device compliance with both Medical Device Regulation (EU) 2017/745 (MDR) requirements and ISO 22442 global standards.

The newest addition to the Biomedical portfolio, Quali-Pure™, is a high-quality gelatin with full documentation to support compliance of your medical device in a global market.

Regulatory Compliance for the successful certification of your product

Quali-Pure™ helps you fulfill the ISO-22442 requirements by providing:

- Full and documented traceability up to the farm (ISO 22442-2)

  Prolonged document retention
- Validated viral inactivation (ISO 22442-3)
- Controlled endotoxin levels (specification upon request)
- Batch-to-batch consistency
- Good Manufacturing Practices (GMP)*

Technical Performance for the successful development of your product

Gelling Quali-Pure	Type	Bloom (g)**	Properties	Applications
Quali-Pure 250P	Acid porcine skin gelatin	250	Tunable rheological properties Can be used in hydrogels, particles or films	Embolization Hemostatic Wound healing Drug delivery
Quali-Pure 300P	Acid porcine skin gelatin	300		
Quali-Pure 300P HV***	Acid porcine skin gelatin	300		

Non-gelling Quali-Pure	Type	MW (Da)	Function	Applications
Quali-Pure HGP 2000****	Acid porcine skin hydrolyzed gelatin	≤ 2000	Surrounds particles and molecules to preserve and aid their function through storage, transportation and administration	Vaccines Parenterals Wound healing Drug delivery

* IPEC. Excipient Good Manufacturing Practices Guide, 2017
** Measured at 6,67%, 10ºC, according to EP/USP
*** High Viscosity
**** Available soon

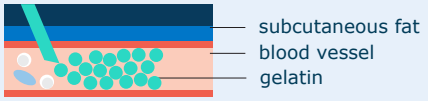
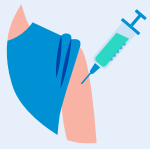
Quali-Pure biomedical gelatin

Biocompatible

Biodegradable

Cell recognition sites to facilitate cell attachment and proliferation

Performance in applications

Embolization	Gelatin particles can be made with different diameters and pore size for different vascular structures and applications.	
Hemostatics	Gelatin is able to act as a hemostatic agent to initiate the wound healing mechanism and to absorb exudates present at the wound region.	
Wound healing	In the proliferative phase, gelatin acts as a porous scaffold to stimulate the migration of cells, specifically fibroblasts, to the injury site. It provides structural and mechanical strength at the wound site to further enhance the formation of new tissues.	
Drug delivery in wound healing	Gelatin can be modified into different forms of drug carriers while preserving its natural properties, and particularly the ability to retain moisture at the wound site.	
Vaccines	Hydrolyzed gelatin represents the major protein/peptide-based excipient in injectable vaccines formulation. It also enables nasal administration of vaccines because it adsorbs easily into mucosal tissue without diminishing a product's immunizing effects.	

Rousselot® Biomedical

As the most recent strategic segment within Rousselot, we have drawn upon Rousselot's 130+ years of worldwide expertise and proven track record of pharmaceutical gelatins and collagens to develop an innovative range of purified modified and non-modified gelatins and collagens for biomedical applications. Offering unique advantages to assure performance, quality and safety from bench to clinic, Rousselot® X-Pure® and Rousselot® Quali-Pure™ provide consistent quality and are backed by strong scientific data and on-going research. Rousselot Biomedical is committed to support end-to-end partnerships to help "advancing medical science". Rousselot is the Darling Ingredients' health brand.