BIOMEDICAL GELATINS FOR HEMOSTATIC DEVICES

THE RELIABLE GELATIN SOLUTIONS

The Rousselot® Biomedical portfolio contains gelatin products specifically designed to meet the functional and regulatory requirements for hemostatic devices accross a broad range of applications. Our X-Pure® and Quali-Pure™ products come with full, documented support regarding regulatory compliance and ISO 22442 requirements. In order to meet the most stringent endotoxin limits in sensitive applications, Rousselot X-Pure offers extremely low endotoxin levels.

X-pure

Quali-pure

Rousselot
Biomedical

Advancing medical science

"EFFECTIVE HEMOSTATICS SAVE LIVES EVERY DAY. ROUSSELOT X-PURE AND ROUSSELOT QUALI-PURE PRODUCTS ENABLE MANUFACTURERS TO PRODUCE SAFE HEMOSTATIC PRODUCTS FOR IN-BODY APPLICATIONS."

LONG HISTORY AS A HEMOSTATIC AGENT

Gelatins are widely used in the hemostatic market due to their biocompatibility, biodegradability and capacity to rapidly absorb human blood. Gelatin can absorb up to 40 times its weight in blood or fluids and can be used in the form of sponges, films or (nano) fibers.

ENHANCED SCRUTINY OF SAFETY DOCUMENTATION

Global standards and regional legislations, such as the ISO 22442 standard and the EU Medical Device Regulation (EU MDR) 2017/745, are introducing additional safety requirements on risk management and traceability for medical devices. From May 2024, all devices placed on the European market will have to conform with the new EU MDR. The use of reliable, safe components is critical for the successful development and certification of your product.

FULL SERVICE OFFER

Our X-Pure and Quali-Pure products fully support medical device compliance with the new EU MDR 2017/745 standards as well as with the ISO 22442 standard. This means these products come with full and documented traceability up to the farm, readily available documentation and prolonged document retention, validated viral inactivation and Good Manufacturing Practices (GMP) - as well as with consistent and controlled endotoxin levels.

THE IMPORTANCE OF PURITY

One of the challenges in applying hemostatic solutions is to avoid exposing the patient's body to endotoxins as these can lead to an immune response. Products in contact with the cardiovascular system, lymphatic system and cerebrospinal fluid therefore can be subject to strict limits regarding the presence of endotoxins.
The use of extremely pure gelatins is vital in these applications. Our X-Pure products offer extremely high purity levels, enabling safety and regulatory compliance for these medical devices.

KEY BENEFITS OF ROUSSELOT BIOMEDICAL GELATINS:

- Full and documented traceability up to the farm (ISO 22442-2:2020)
- Validated viral inactivation (ISO 22442-3:2007)
- Controlled purity and endotoxin levels
- Batch-to-batch consistency
- Good Manufacturing Practices (IPEC-PQG GMP 2017)
- Excellent absorption capacity: gelatin can absorb up to 40 times its weight in blood, and can expand by 200%
- Biocompatible and biodegradable
- Gelatin-based products reach fast and efficient hemostasis
- Easily grindable for syringe application, for instance, if you want to combine gelatin with thrombin
- Suitable for both human and veterinary hemostatic applications.

Gelatins	Type	Endotoxin level (EU/g)[1]	Gel strength*(g)[2]	Application
X-Pure® 10P	Acid porcine skin gelatin	Extremely low endotoxin levels ≤10	300-400	Cardiovascular system, lymphatic system, cerebrospinal fluid
X-Pure® 10B	Lime bovine bone gelatin	Extremely low endotoxin levels ≤10	240-360	Cardiovascular system, lymphatic system, cerebrospinal fluid
Quali-Pure™ 250P	Acid porcine skin gelatin	Specification upon request	250	Hemostatic devices
Quali-Pure™ 300P	Acid porcine skin gelatin	Specification upon request	300	Hemostatic devices
Quali-Pure™ 300P HV	Acid porcine skin gelatin	Specification upon request	300	Hemostatic devices

**Measured at 6.67% gelatin solution, 10°C.*

References

[1] These levels are determined by means of the Charles River LAL (Limulus Amebocyte Lysate) assay, an FDA compliant method
[2] Gelling gelatins according to EP/USP

@RousselotBio Rousselot

rousselot.com/biomedical

For more information and/or an experimental sample

CONTACT US!
rousselot.com/contact

Rousselot B.V.
Kanaaldijk Noord 20
5691 NM Son - The Netherlands
+31 499 364 100