



A FULL RANGE OF LOW-ENDOTOXIN GELATINS FOR REGENERATIVE MEDICINE

UNLOCKING CLINICAL TRANSLATION FOR GELATIN-BASED BIOMATERIALS

Health care and medicine have been widely transformed in recent years by the development of new transplantable biomaterials for applications such as tissue engineering, 3D cell culture applications or drug delivery. Gelatins and modified gelatins are particularly well suited for regenerative medicine applications since they combine inherent biological characteristics with tunable mechanical properties.

Rousselot® has developed a unique range of biomedical gelatins offering the quality needed for use in clinical trials: Rousselot's X-Pure® gelatins and modified gelatins are consistent in their physical and chemical properties, are GMP-ready and have the required level of purity.

X-PURE®, A UNIQUE, GLOBAL ONE-STOP BRAND OF GELATINS AND MODIFIED GELATINS FOR REGENERATIVE MEDICINE

GELATIN, A HIGHLY FAVORED BIOMATERIAL

One of the challenges in the field of regenerative medicine is the generation of suitable biomaterials that closely mimic the body's own matrix. Gelatin fits this profile: gelatin-based hydrogels provide favorable cell growth conditions, while gelatin-based delivery systems are well suited for the targeted release of compounds like interferon, antibiotics, siRNA, growth factors and anticancer medicine.

OUR PRODUCT RANGE INCLUDES:

- **X-Pure®**: ultra-purified gelatins and collagens, gelling and non-gelling (hydrolyzed) gelatins
- **X-Pure® GelMA**: the world's first GMP-ready gelatin methacryloyl for regenerative medicine and one of the preferred biomaterials, due to its guaranteed ultra-low impurity levels and tunable mechanical properties.
- **X-Pure® GelDAT**: the world's first purified gelatin desaminotyrosine, ideal for developments in regenerative medicine, drug delivery and complex wound dressings, due to its dual crosslinking cues and ability to crosslink with human tissues.

| Gelatins | Type | Endotoxin level (EU/g) | gel strength* (g) |
|-------------------|---------------------------|------------------------|-------------------|
| X-Pure® 100P LBLV | Acid porcine skin gelatin | ≤100 | 100 - 180 |
| X-Pure® 10P HBLV | Acid porcine skin gelatin | ≤10 | >300 |
| X-Pure® 10P HBHV | Acid porcine skin gelatin | ≤10 | >300 |
| X-Pure® 10B HBHV | Lime bovine bone gelatin | ≤10 | >300 |

| Hydrolyzed Gelatins | Type | Endotoxin level (EU/g) | MW (kDa) |
|---------------------|--------------------------------------|------------------------|----------|
| X-Pure® 10HGP 6500 | Acid porcine skin hydrolyzed gelatin | ≤10 | ≤6.5kDa |

| Modified gelatins | MW (kDa) | DoM (%) | Endotoxin level (EU/g) | MA/DAT (ppm) |
|----------------------|----------|---------|------------------------|--------------|
| X-Pure GelMA 160P40 | 160 | 40 | ≤ 10 | ≤ 30 |
| X-Pure GelMA 160P60 | 160 | 60 | ≤ 10 | ≤ 30 |
| X-Pure GelMA 160P80 | 160 | 80 | ≤ 10 | ≤30 |
| X-Pure GelMA 90P60 | 90 | 60 | ≤ 10 | ≤ 30 |
| X-Pure GelMA custom | Custom | Custom | ≤ 10 | ≤ 30 |
| X-Pure GelDAT custom | Custom | Custom | ≤ 10 | ≤30 |

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

DoM: Degree of Modification

MW: Molecular Weight

MA: Methacrylic Acid (reaction byproduct)

DAT: Desaminotyrosine (reaction byproduct)

LOW-ENDOTOXIN GELATIN CAN IMPROVE RESEARCH OUTCOMES AND PATIENT SAFETY

Endotoxins have been shown to trigger unfavorable immune response in in-body applications and also to negatively affect cell growth and cell differentiation *in-vitro*¹. Low-endotoxin gelatins provide the best possible purity and safety profile and can therefore significantly improve research outcomes and patient safety.



KEY BENEFITS OF ROUSSELOT® X-PURE® GELATINS AND MODIFIED GELATINS:

General gelatin benefits

- Natural and biocompatible, blends easily with other biopolymers
- Compliant with the US, European and Japanese pharmacopeia
- Non-immunogenic
- Presence of RGD (Arginine-Glycine-Aspartic acid) cell recognition sequences for integrin-mediated cell attachment.

X-Pure benefits

- A full range of ultra-purified² gelatins and modified gelatins suitable for regenerative medicine applications
- Functional equivalence between Research and GMP grades helping reduce development timelines
- The possibility to customize X-Pure products to the molecular weight, degree of modification or bloom. On request.
- Biodegradable. Controlled biodegradability for X-Pure GelMA and X-Pure GelDAT.

References

¹ Sivasubramaniyan, et al., 2008, Regen. Med, 3(1): 23-31

² These levels are determined by means of the Charles River LAL (Limulus Amebocyte Lysate) assay, an FDA compliant method

For more information and/or an experimental sample

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