



X-PURE® 10P HBHV

(BIO)MEDICAL APPLICATION

Product description

X-PURE® 10P HBHV is an acid gelatin extracted from pig skin and specifically designed for applications requiring intensely purified biomaterials, such as hemostatic products, parenteral formulations (including vaccines) and regenerative medicine.

X-PURE® 10P HBHV comes with low endotoxin levels, making it the perfect solution for (bio)medical applications^(*).

() It should not be construed as a guarantee of suitability for a particular application.*

*(**) LAL assay (Limulus Amebocyte Lysate), a FDA compliant method*

*(***) GME, Gelatine Manufacturers of Europe*

Physical/chemical/microbial limits

Standard parameters	Specifications	Test Method
Endotoxin level	≤ 10 EU/g	LAL assay**
Gel strength (6.67%, 10°C, 17H)	> 300 g	EP, USP
Viscosity (6.67%, 60°C)	5.2 – 6.8 mPa.s	GME***
pH (1%, 55°C)	4.5 – 5.5	EP, USP
Loss on drying	≤ 7.0%	EP, USP
Conductivity	≤ 500 µS.cm ⁻¹	EP, USP
Residue limits		
Iron	≤ 30 ppm	EP, USP
Chromium	≤ 10 ppm	EP, USP
Zinc	≤ 30 ppm	EP, USP
Arsenic	≤ 0.8 ppm	EP, USP
Heavy metals	≤ 20 ppm	EP, USP
Sulfites (SO ₂)	≤ 20 ppm	EP, USP, JP
Peroxides	≤ 10 ppm	EP, USP
Microbial limits	Specifications	Test Method
Total aerobic microbial count-TAMC	≤ 100 CFU/g	EP, USP
Total yeasts and molds-TYMC	≤ 10 CFU/g	EP, USP
Salmonella	Absence in 10g	EP, USP
E. coli	Absence in 1g	EP, USP
Pseudomonas aeruginosa	Absence in 1g	EP, USP
Staphylococcus aureus	Absence in 1g	EP, USP

Labeling information

This product has to be declared on labels as gelatin.

Packaging

Internal PE sterile bag enclosed in an aluminum bag.
Quantity 500g, 50g and 10g. Additionally, the 10g and 50g are primary packed in a PET or PETG flask.

Storage information

Store away from heat and moisture. When stored in the previously mentioned conditions and in its original unopened packaging, this product will maintain its initial properties for at least 5 years.

Caution: Close the recipient immediately after use.

Regulatory status

X-PURE® 10P HBHV complies with most international pharmaceutical regulations including the US, European and Japanese pharmacopoeia – monograph (purified) gelatin - and their latest modifications in force at the date of issue of this data sheet.

However, we recommend that the customer ensures that this product is in compliance with local regulations in force, particular in countries where the finished products are used.

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 innovative ranges 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™ 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 Darling Ingredients' Health Brand.



Supplier

Rousselot BV
Meulestedekaai 81 – 9000 Gent – Belgium
Tel: + 32 (0)9 255 18 18 Fax: + 32 (0)9 251 64 51

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