



X-PURE® 10P MBMV

Research grade

Product description

X-Pure® 10P MBMV 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 MBMV comes with low endotoxin levels, making it a perfect solution for (bio)medical applications(*).

X-Pure® research grade materials are functionally equivalent to the GMP grade materials but are intended for research purposes only.

Research grade materials are not intended for use in human or animal therapeutic applications.

Physical/chemical/microbial limits

Standard parameters	Typical values	Test Method
Endotoxin level	≤ 10 EU/g	LAL assay**
Gel strength (6.67%, 10°C, 17H)	140 – 210 g	EP, USP
Viscosity (6.67%, 60°C)	1,8 – 3,0 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
Microbial parameters	Typical values	Test Method
Total aerobic microbial count-TAMC	≤ 100 CFU/g	EP, USP
Total yeasts and molds-TYMC	≤ 10 CFU/g	EP, USP
<i>Salmonella</i>	Absence in 10g	EP, USP
<i>E. coli</i>	Absence in 1g	EP, USP
<i>Pseudomonas aeruginosa</i>	Absence in 1g	EP, USP
<i>Staphylococcus aureus</i>	Absence in 1g	EP, USP

(*) 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*

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.

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 "Improving patients' lives".

Rousselot is Darling Ingredients' Health Brand.



Supplier

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