



X-PURE® 10HGP 6500

(BIO)MEDICAL APPLICATION

Product description

X-Pure 10HGP 6500 is a non-gelling gelatin extracted from pig skin suitable for vaccine and injectable applications.

X-Pure 10HGP 6500 comes with low endotoxin levels, making it the perfect solution for (bio)medical applications^(*).

Physical/chemical/microbial limits

Standard parameters	Specifications	Test Method
Endotoxin level	≤ 10 EU/g	LAL assay**
Molecular weight	≤ 6500 Daltons	Rousselot
pH (1%, 55°C)	4.0 – 5.5	EP, USP
Loss on drying	≤ 7.0%	EP, USP
Conductivity	≤ 1000 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

() 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 non-gelling or hydrolyzed 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 10HGP 6500 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

Non contractual document, specifications presented can be changed without prior notice. Ensure you use latest version / Reference PDS-BIOMED-10005 Revision: 4 Date: Oct 24, 2022 © Rousselot BV - Pictures: © Rousselot /

rousselot.com/biomedical

Rousselot
Biomedical