



LOW-ENDOTOXIN GELATINS: A NEW STANDARD FOR PARENTERAL FORMULATIONS



PUREST AND SAFEST GELATIN ON THE MARKET FOR PARENTERAL FORMULATIONS

A new excipient for parenteral formulations is available now that is purer than all the gelatin alternatives on today's market: Rousselot's X-Pure® 10 HGP. Our validated purification process guarantees consistent quality between batches.



THE WORLD'S FIRST & ONLY LOW-ENDOTOXIN GELATIN FOR PARENTERAL FORMULATIONS

" PARENTERAL PRODUCTS SAVE LIVES EVERY DAY. X-PURE'S LOW-ENDOTOXIN LEVELS PROVIDE YOU WITH THE SAFEST EXCIPIENTS FOR THESE LIFE-SAVING MEDICAL PRODUCTS."

X-PURE® 10 HGP: A NEW GLOBAL PURITY STANDARD IN EXCIPIENTS FOR PARENTERAL FORMULATIONS

Gelatin has been a trusted excipient in the pharmaceutical industry for decades and is used as a stabilizer in many different delivery forms, such as parenteral formulations. These include vaccines and other injectables, in which the purity of the excipient is crucial for patient safety. With X-Pure® 10 HGP, Rousselot has set a new global standard for purity in parenteral dosage forms.

DEMAND FOR SAFE EXCIPIENTS IS GROWING WORLDWIDE

Today's vaccine industry is growing rapidly, with government organizations launching increasing numbers of vaccination programs around the world to combat the rising prevalence of (infectious) diseases. This means demand for excipients that can ensure patient safety after administration of a vaccine is higher than ever before.

X-PURE, A HIGHLY PURIFIED AND EXCEPTIONALLY SAFE SOLUTION

Being part of Rousselot X-Pure range, X-Pure® 10 HGP is a highly purified acid treated gelatin of porcine origin, offering endotoxin levels that are unrivalled in the market. For parenteral formulations, X-Pure is available in hydrolyzed form (non-gelling gelatin according to EP/USP). Check the table below for details.

	Type	Molecular weight (kDa)	Endotoxin level (EU/g)
X-Pure® 10 HGP	Acid porcine skin hydrolyzed gelatin	≤6.5kDa	≤10

References

¹ These levels are determined by means of the Charles River LAL (Limulus Amebocyte Lysate) assay, an FDA compliant method



KEY BENEFITS OF ROUSSELOT® X-PURE®:

X-Pure® 10 HGP is a highly purified, hydrolyzed gelatin of porcine origin that offers numerous benefits over alternative excipients for parenteral formulations, both for patients and for product developers.


Patient benefits

- Unrivalled safety as the first hydrolyzed acid porcine skin gelatin on the global market with endotoxin levels below 10 Endotoxin Units per gram (EU/g), or even below LAL analysis detection limits¹ if required
- Biodegradable and therefore absorbable
- A substance of natural origin, well tolerated by the human body and biocompatible.

Manufacturing benefits

- Purified by Rousselot proprietary and validated process
- Maximum quality consistency
- Generally Recognized As Safe (GRAS) by the USA's Food and Drug Administration (FDA) and compliant with the US and European pharmacopeia
- Suitable for both human and veterinary applications.

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For more information and/or an experimental sample of X-Pure®, please contact us at:

Rousselot Headquarters

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