THE WORLD'S FIRST & ONLY LOW-ENDOTOXIN GELATIN 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. Because we purify it following a validated process, product developers also benefit from consistent quality.

Reaching Further Together
"PARENTERAL PRODUCTS SAVE LIVES EVERY DAY. X-PURE’S LOW-ENDOTOXIN LEVELS ENABLE YOU TO MANUFACTURE 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 safely carry the vaccine into the patient’s body is higher than ever before.

X-PURE, A HIGHLY PURIFIED AND EXCEPTIONALLY SAFE SOLUTION

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.

<table>
<thead>
<tr>
<th>Type</th>
<th>Molecular weight (kDa)</th>
<th>Endotoxin level (EU/g)</th>
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<tbody>
<tr>
<td>X-Pure® 10 HGP</td>
<td>Acid porcine skin hydrolyzed gelatin</td>
<td>≤6.5kDa</td>
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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 limits if required
- Biodegradable and therefore absorbable
- A substance of natural origin, well tolerated by the human body and biocompatible.

Manufacturing benefits
- Purified by Rousselot 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 pharmacopoeia
- Suitable for both human and veterinary applications.

For more information and/or an experimental sample of X-Pure®, please contact us at:
Rousselot B.V. Kanaaldijk Noord 20 5691 NM Son The Netherlands
+31 499 364 100 gelatin@rousselot.com

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