



**X-PURE® &
QUALI-PURE™**

*GELATINS FOR
VACCINE FORMULATION*

RELIABLE GELATIN SOLUTIONS FOR VACCINES

Rousselot® Biomedical portfolio offers hydrolyzed gelatins specifically designed to meet the functional and regulatory requirements for vaccines. Assuring high levels of purity and batch-to-batch consistency, X-Pure® and Quali-Pure™ provide vaccine manufacturers with the quality and safety levels they expect and require.



Advancing medical science

Rousselot

Biomedical

Darling Ingredients' Health Brand

"VACCINES ARE KEY IN PREVENTING INFECTIOUS DISEASES. ROUSSELOT'S X-PURE® AND QUALI-PURE™ HYDROLYZED GELATINS ARE CONSISTENT EXCIPIENTS IDEAL FOR USE IN VACCINES."

GELATIN, A ESTABLISHED EXCIPIENT IN VACCINE FORMULATIONS

Today's vaccine industry is growing rapidly, driven by the global Covid-19 pandemic and the rising focus on immunization programs worldwide¹.

Gelatin has been a trusted excipient in the pharmaceutical industry for decades. Owing to its biocompatible and biodegradable nature, it has long been used as a safe and effective stabilizing agent to protect vaccines against the effects of temperature.

THE IMPORTANCE OF PURITY

Endotoxins are increasingly recognized by authorities around the world as important impurities that must be controlled in parenteral applications. Endotoxin limits in vaccines are largely harmonized among the leading Pharmacopeia (USP/EP/JP/ChP) and Health Authorities (FDA, EMA, PMDA, SFDA). Depending on the route of administration, the limit values set for endotoxin are based on the human tolerance levels for endotoxins (in EU/kg of body weight). For vaccines administered through injection, a limit of 5.0EU/kg body weight is typically applied.

A FULL-SERVICE OFFER

Endotoxin limits for finished dosage forms will depend on the volume and composition of the product in question. Rousselot's X-Pure and Quali-Pure range of hydrolyzed gelatins offers an excipient with controlled endotoxin levels adjusted to your vaccine preparation. With endotoxin levels below 10EU/g², our X-Pure HGP helps to adhere to the most stringent endotoxin requirements. X-Pure and Quali-Pure come with readily available documentation and prolonged document retention, validated viral inactivation and Good Manufacturing Practices (GMP).



KEY BENEFITS OF X-PURE AND QUALI-PURE:

- Controlled purity and endotoxin levels, enabling compliance with leading Pharmacopeia and Health Authorities
- High batch-to-batch consistency
- Good Manufacturing Practices IPEC-GMP (ISO 9001: 2015 certified)
- Suitable for both human and veterinary vaccine formulations
- Full and documented traceability up to the farm (ISO 22442-2:2020)
- Validated viral inactivation (ISO 22442-3:2007)
- Support from our scientific and regulatory experts

Gelatins	Type	Molecular weight (kDa)	Endotoxin level (EU/g)	RNase free
X-Pure® 10 HGP	Type A hydrolyzed gelatin from porcine skin	≤6.5kDa	≤10	Yes
Quali-Pure™ HGP	Type A hydrolyzed gelatin from porcine skin	≤2.0kDa	Specification upon request	No

References

¹ <https://www.pharmaceutical-technology.com/sponsored/cdmos-vaccine-industry-overview/>

² These levels are determined by means of the Charles River LAL (Limulus Amebocyte Lysate) assay, an FDA compliant method



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For more information and/or
an experimental sample:

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