



DELIVERING SECURE SUPPLY WITH THE RIGHT PARTNER

BIOPHARMA



ROQUETTE

Offering the best of nature™

TRUST—IT'S THE MOST ESSENTIAL INGREDIENT

To facilitate your successful biopharmaceutical formulation, we remain dedicated to delivering the highest-quality multi-compendial grade materials through our sole custody of the supply chain. To support biologic drug innovators and visionaries like you, our in-process quality control ensures a consistent supply of raw materials and excipients that help bring your biologics to life.

PRODUCT INFORMATION

PRODUCT	DESCRIPTION	PACKAGE SIZE	PRODUCT CODE
PEARLITOL® BioPharma	Mannitol, low endotoxin, USP, EP, JP. Suitable for use in biopharmaceutical manufacturing and as an excipient for injectable dosage forms.	12 kg	450003103X
		25 kg	450003104Y
		50 kg	450003105Z
NEOSORB® BioPharma	Sorbitol, low endotoxin, USP, EP, JP, ChP. Suitable for use in biopharmaceutical manufacturing and as an excipient for injectable dosage forms.	12 kg	423127103N
		25 kg	423127104P
		50 kg	423127105R
LYCADEX® BioPharma	Dextrose monohydrate, low endotoxin, USP, EP, JP. Suitable for use in biopharmaceutical manufacturing.	12 kg	361125103J
		25 kg	361125104K
		50 kg	361125105L
Dextrose Anhydrous BioPharma	Dextrose anhydrous, USP, EP, JP, FCC. Suitable for use in cell culture applications.	12 kg	361417102T
		25 kg	361417103W
		50 kg	361417104X

QUALITY ATTRIBUTES

Our products comply with the corresponding regulation or other requirements. Additional information is available in Quality Statements or Quality Technical Documentation.

ATTRIBUTE	REGULATION
cGMP	ICH-Q7 or IPEC PQG GMP*
Supply Chain Integrity / Transparency	IPEC Good Distribution Practices Guide for Pharmaceutical Excipients
Aflatoxins	(EC) No 1881/2006
Allergens	(EC) No 1169/2011
Conflict Minerals	Section 1502 of the U.S. Dodd-Frank Act**
Dioxin	(EC) No 1881/2006, (EU) No 1259/2011
Elemental Impurities	ICHQ3D
Genotoxic Impurities	ICHM7***
GMO	(EC) No 1829/2003, (EC) No 1830/2003
Metal Catalysts	EMEA/CHMP/SWP/4446/2000
Nanoparticles	(EC) No 1169/2011**
Pesticides	(EC) No 396/2005
Residual Solvents	ICHQ3C***

ATTRIBUTE	ADDITIONAL REQUIREMENTS
Animal Origin	No TSE/BSE**
Ethylene Oxide	**
Ionizing Radiation	**
Latex	****
Melamine	***
Viral Safety	**

*Depending on the product, manufacturing site inspected by FDA and ANSM and found to be in compliance.

**Not used in the manufacturing process

***Neither used nor generated in the manufacturing process

****Not generated in the manufacturing process



LEARN MORE ABOUT ROQUETTE BIOPHARMA PRODUCTS AT
www.roquette.com | pharma@roquette.com


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