



# DELIVERING SECURE SUPPLY WITH THE RIGHT PARTNER

BIOPHARMA



**ROQUETTE**

Offering the best of nature<sup>®</sup>

## 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
<b>PEARLITOL® BioPharma</b>	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
<b>NEOSORB® BioPharma</b>	Sorbitol, low endotoxin, USP, EP, JP. Suitable for use in biopharmaceutical manufacturing and as an excipient for injectable dosage forms.	12 kg	423127103N
		25 kg	423127104P
		50 kg	423127105R
<b>LYCADEX® BioPharma</b>	Dextrose monohydrate, low endotoxin, USP, EP, JP. Suitable for use in biopharmaceutical manufacturing.	12 kg	361125103J
		25 kg	361125104K
		50 kg	361125105L
<b>Dextrose Anhydrous BioPharma</b>	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](http://www.roquette.com) | [pharma@roquette.com](mailto:pharma@roquette.com)