



DELIVERING SECURE SUPPLY WITH THE RIGHT PARTNER

CELL CULTURE SOLUTIONS



ROQUETTE

Offering the best of nature™

TRUST – COMPLETE SUPPLY CHAIN TRACEABILITY

With sole custody of the supply chain, we offer confidence straight from the source when it comes to meeting the carbohydrate needs of your cell culture process. Our Dextrose Solutions offer fiber free packaging in a variety of sizes to suit your needs, in-process control to ensure quality consistency, integrated manufacturing and change management control to ensure reliability in your process. LYCADEX® Biopharma Dextrose Monohydrate is manufactured under ICHQ7 and is endotoxin controlled. Dextrose Anhydrous Biopharma is manufactured under GMP IPEC guidelines and is endotoxin monitored.

Trust in Roquette to help bring your biologics to life with Dextrose Anhydrous BioPharma and LYCADEX® Biopharma Dextrose Monohydrate.

PRODUCT INFORMATION

PRODUCT	DESCRIPTION	PACKAGE SIZE	PRODUCT CODE
LYCADEX® BioPharma	-Dextrose monohydrate -Low endotoxin (endotoxin controlled) -USP, EP compliance -Suitable for use in cell culture, fill and finish applications	12 kg	361125103J
		25 kg	361125104K
		50 kg	361125105L
Dextrose Anhydrous BioPharma	-Dextrose anhydrous -Endotoxin monitored -USP, EP, JP, FCC, ACS compliance -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 and regulatory requirements. Additional information is available in Quality Statements or Quality Technical Documentation.

ATTRIBUTE	REGULATORY COMPLIANCE
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**
Elemental Impurities	ICHQ3D Section 5***
Genotoxic Impurities	ICHM7**
Metal Catalysts	EMEA/CHMP/SWP/4446/2000
Residual Solvents	ICHQ3C**

ATTRIBUTE	ADDITIONAL REQUIREMENTS
Animal Origin	No TSE/BSE**
Ethylene Oxide	**
Residual Solvent: Class 1, 2, 3	**
Latex	**
Melamine	**
Viral Safety	**

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

**Neither used nor generated in the manufacturing process

***As relevant to drug product manufacturers incorporating Roquette excipients in their formulation.

*Roquette BioPharma, bringing new solutions for stability.
Financial. Supply. Protein.*



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


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