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CERTIFICATE OF ANALYSIS

Product: D-Galactose	Mfg. date: Mar., 03, 2024	Lot No.: 20240303
CAS NO. 59-23-4	Exp. date: Mar., 02, 2027	Quantity: 700kg

Items	Specifications	Results
Appearance	White or almost white powder	Conforms
Identification 1. Infrared Spectroscopy 2. Thin-Layer C 3. Reduction Reaction	Correspond to the IR spectrum of RS. The principal spot of the test solution should be similar in position, color and size to that of reference solution Dissolve 0.1g in 10mL of water, add 3 mL of cupri-tartaric solution and heat. An orange or red precipitate should be formed.	Conforms
Appearance of Solution	Solution should be clear and should be light to reference solution B ₈	Conforms
Acidity or Alkalinity	Not more than 1.5 mL of 0.01 M sodium hydroxide is required to a pink color.	0.4ml
Water	≤0.5%	0.2%
Specific Rotation	+78 ~ +81.5 °	+79.8 °
Barium	Any opalescence in the solution should not be more intense than that in a mixture.	Conforms
Lead	≤0.5mg/kg	0.2mg/kg
Heavy metals	≤5mg/kg	Conforms
Residue on ignition	≤0.1%	0.05%
Methanol	≤200mg/kg	Not detected
Ethanol	≤200mg/kg	15mg/kg
Proteins	≤0.1mg/ml	Conforms
Endotoxin	≤10EU/g	<10EU/g

Assay(HPLC) D-(+)-Galactose	98%~102%	100.0%
Lactose+1.6-galactosylgalactose	≤0.6%	<0.1%
Galacturonic acid	≤0.3%	Not detected
Arabinose	≤0.3%	0.1%
Any Unspecified Impurity	≤0.2%	0.2%
Total Impurities	≤1.0%	0.4%
Total Aerobic Count	< 100cfu/g	Conforms
Moulds and Yeasts	< 100cfu/g	Conforms
E.Coli	Negative	Not detected
Salmonellae	Negative	Not detected
Staphylococcus Aureus	Negative	Not detected
Purity(HPLC) D-(+)-Galactose	≥99.0%	99.5%
Conclusion	The product conforms to the standard of USP43&EP10.	

QC:



Tester:



Re-tester:

