



Certificate of Analysis

Product	88539 - Lactose Monohydrate sterile (gamma irradiated) - [10039-26-6, 64044-51]	
Batch No	3350121	
Analysis Date	02-May-2024	
Date of Manufacture	May 2024	
Expiry Date/Re-Test Date	May 2026	
Molecular Formula	C ₁₂ H ₂₂ O ₁₁ .H ₂ O	
Molecular Weight	360.31	
Test Parameters	Standards	Actual Results
Appearance (Colour)	White crystalline	Complies
Appearance (Form)	Free flowing, fine powder	Complies
Solubility	10% aq. solution is completely soluble	Complies
Clarity of solution	10% w/v aqueous solution is clear and colourless	Complies
pH (25°C)	(10% aq.) 4.00 - 6.00	4.34 Complies
Residue on ignition	Max 0.03%	Complies
Chloride (Cl)	Max 0.005%	Complies
Sulphate (SO ₄)	Max 0.005%	Complies
Heavy Metals (Pb)	Max 0.0001%	Complies
Dextrose	Passes test	Complies
Sucrose	Passes test	Complies
Acidity	Max. 0.25 ml	Complies
Nitrogen Compounds (N)	Max. 0.02%	Complies
Water (KF)	4.8 - 5.4%	Complies
Absorbance (A) of 1% aq. solution in a 1cm cell v/s H ₂ O	@210 - 220 nm max. 0.25 @270 - 300 nm max. 0.07	Complies
Sterility (Bacterial count)	No growth is observed after 14 days for bacteria at 30 - 35°C and for fungi at 20 - 25°C	Complies
Cultural Response	Cultural response observed after an incubation at 35 ± 2°C for 18 - 24 hours by preparing Phenol Red Broth Base (14517) using 0.5% of Lactose monohydrate, Sterile (Gamma Irradiated)	
Organism	Enterobacter aerogenes ATCC 13048	
Inoculum (cfu) 10-100	Growth : Good, Acid : + , Gas production : +	Complies
Organism	Escherichia coli ATCC 25922	
Inoculum (cfu) 10-100	Growth : Good, Acid : + , Gas production : +	Complies



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Molecular Formula

C₁₂H₂₂O₁₁.H₂O

Molecular Weight

360.31

Test Parameters

Standards

Actual Results

Organism

Proteus vulgaris ATCC 13315

Inoculum (cfu) 10-100

Growth : Good, Acid : --- , Gas
production : ---

Complies

Organism

Salmonella typhimurium ATCC 14028

Inoculum (cfu) 10-100

Growth : Good, Acid : --- , Gas
production : ---

Complies

Organism

Pseudomonas aeruginosa ATCC 27853

Inoculum (cfu) 10-100

Growth : Good, Acid : --- , Gas
production : ---

Complies

FRM/82/11/3/88539 Rev No. 1 Date 15/06/2021

Prepared by Shikha

In compliance with the standard specifications of SRL

Plant Site 1 : D-88/2, MIDC, Turbhe – 400 705, New Mumbai, India

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