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Certificate of Analysis

Product	25957 - Lactose Monohydrate ACS - [10039-26-6, 64044-51]
Batch No	7602463
Analysis Date	29-Apr-2024
Date of Manufacture	April 2024
Expiry Date/Re-Test Date	April 2029
Molecular Formula	C ₁₂ H ₂₂ O ₁₁ .H ₂ O
Molecular Weight	360.31

Test Parameters	Standards	Actual Results
Appearance (Colour)	White	White
Appearance (Form)	Crystalline powder	Crystalline powder
Solubility (Turbidity) 10% aq. solution	Clear	Clear
Solubility (Colour) 10% aq. solution	Colourless	Colourless
Sulphated Ash	max. 0.05%	0.002%
Chloride (Cl)	max. 0.005%	Passes
Sulphate (SO ₄)	max. 0.005%	Passes
Iron (Fe)	max. 0.0002%	Passes
Heavy Metals (Pb)	max. 0.0001%	Passes
Copper (Cu)	max. 0.00005%	Passes
Arsenic (As)	max. 0.0001%	Passes
Nitrogen Compounds (N)	max. 0.02%	Passes
Acidity	max. 0.25ml N%	0.12 mlN%
Specific rotation [α] (As is basis)	+52° to +52.8° (C = 10, water)	+52.3°
Specific Rotation [α] (Anhydrous basis)	+54.4° to +55.9° (C = 10, water)	+55.2°
Water (KF)	4.8 - 5.4%	4.9%
Absorbance (A) of 1% aq. solution in a 1cm cell v/s H ₂ O		
@210-220nm	max. 0.25	0.062
@270-300nm	max. 0.07	0.027

FRM/82/11/4/25957 Rev No. 3 Date 03/03/2024

Prepared by Prasad

In compliance with the standard specifications of SRL

Plant Site 2 : H-4, MIDC, Talaja – 410 208, Maharashtra, India

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