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Certificate of Analysis

Product **67091 - Lactose Monohydrate ACS, ExiPlus,
Multi-Compendial - [10039-26-6, 64044-51]**

Batch No **1232454**
Analysis Date 29-Apr-2024
Date of Manufacture April 2024
Expiry Date/Re-Test Date April 2029
Molecular Formula C₁₂H₂₂O₁₁.H₂O
Molecular Weight 360.31

Test Parameters	Standards	Actual Results
ExiPlus	meets compendial specs of USP, BP & Ph Eur	Passes
Appearance (Colour)	White	White
Appearance (Form)	Crystalline powder	Crystalline powder
Solubility (Turbidity) 10% aq. solution	Clear	Clear
Solubility (Colour) 10% aq. solution	Colourless	Colourless
Insoluble matter	max. 0.005%	0.001%
Specific Rotation [α] (Anhydrous basis)	+54.4° to +55.9° (C = 10, water) at 20 °C	+55.2°
Residue on ignition	max. 0.03%	0.002%
Iron (Fe)	max. 0.0005%	Passes
Heavy Metals (Pb)	max. 0.0005%	Passes
Arsenic (As)	max. 0.0001%	Passes
Dextrose	Passes test	Passes
Sucrose	Passes test	Passes
Acidity or alkalinity	max. 0.3 ml	0.1 ml
Water (KF)	4.0 - 6.0%	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
IR Identification Test	Passes test	Passes

FRM/82/11/4/67091 Rev No. 6 Date 18/04/2024

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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