



大连汉德姆精细化学品有限公司

DALIAN HANDOM CHEMICALS CO.,LTD.

Certificate of Analysis

Product Name: Lactose Monohydrate

CAS No.: 5989-81-1

Batch No.: HDC20230815

Particle Size: 200mesh

Batch Quantity: 14500kg

Packing: Polyethylene/paper-plastic composite bag

MFG. Date: Aug 15th, 2023

Retest Date: Aug 14th, 2025

Report Date: Aug 16th, 2023

Standard: USP42/CP2020/EP8.0

Test Items	Specifications	Test Results
Appearance	White free-flowing powder	White powder
Solubility	Freely but slowly soluble in water, practically insoluble in alcohol	Conforms
Identification	(1) The retention of the main peak of the test solution in the chromatogram recorded under the content determination item should be consistent with the retention time of the main peak of the reference solution.	Conforms
	(2) The infrared light absorption profile of the product should be consistent with that of the control.	Conforms
Optical Rotation	+54.4° ~ +55.9°	+55.2°
Acidity/Alkalinity	Take 6.0g of this product and check according to law, the solution is colourless, and not more than 0.4ml of 0.1 N sodium hydroxide is required to produce a pink to red colour.	Conforms
Clarity and Colour of Solution	Take 1.0g of this product, add 10ml boiling water to dissolve, check according to law, the solution should be clear and nearly colourless.	Conforms
	Take this product, determine according to law, measure absorbance at 400nm wavelength, not more than 0.04	<0.01
Protein and impurity absorbance	210nm ~ 220nm: Not more than 0.25	<0.04
	270nm ~ 300nm: Not more than 0.07	<0.02
Loss on Drying	Not more than 0.5%	<0.14%
Water	4.5% ~ 5.5%	5.00%
Residue on Ignition	Not more than 0.1%	0.01%



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Heavy Metals	Not more than 5ppm	Conforms
Arsenic Salt	Take the residue under the burning residue, check according to law, should comply with the regulations (0.0002%).	Conforms
Total Aerobic Microbial Count	Not more than 100CFU/g	<10CFU/g
Total Yeasts and Moulds Count	Not more than 50CFU/g	<10CFU/g
Escherichia coli	Negative/g	Not detected
Content	The chemical name of this product is 4-O-beta-D-Galactopyranosyl-D-glucose. Containing C ₁₂ H ₂₂ O ₁₁ should be between 98.0% and 102.0%.	99.50%
Rotap Particle Size	Not less than 80% pass through 75μm sieve	85%
	Not less than 99% pass through 150μm sieve	99%

Conclusion: The testing results of this batch are complied with the standards of USP42/CP2020/EP8.0.