



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 Anhydrous  
**Manufacturing Date:** Nov 18<sup>th</sup>, 2022  
**Quantity:** 800kg  
**Report Date:** Nov 19<sup>th</sup>, 2022

**Batch No.:** HDC20221118  
**Retest Date:** Nov 17<sup>th</sup>, 2024  
**Packing:** 25kg/bag  
**Standard:** USP40

Test Item	Specification	Test Result
Appearance	White or almost white crystalline powder	Conforms
Solubility	Freely but lowly soluble in water, practically insoluble in ethanol(96%)	Conforms
Identification A	The infrared absorption spectrum of the sample is concordant with that of the standard.	Conforms
Identification B	The principal spot obtained from the Test solution corresponds in appearance and R <sub>F</sub> value to that obtained from Standard solution A. The test is not valid unless the chromatogram obtained with Standard solution B shows four clearly discernible spots, disregarding any spots at the origin.	Conforms
Residue on Ignition	Not more than 0.1%	0.03%
Heavy Metals	Not more than 5 µg per g	Conforms
Clarity and Colour of Solution	The solution(1g in 10 ml of boiling water) is clear and nearly colourless.	Conforms
	Determine the absorbance of this solution at a wavelength of 400 nm. The absorbance divided by the path length, in cm, which is not more than 0.04.	0.03
Optical Rotation	+54.4°~ +55.9°, calculated on the anhydrous basis, determined at 20°C	+54.94°
Acidity or alkalinity	Adding 0.3 ml of phenolphthalein TS: the solution is colourless, and not more than 0.4 ml of 0.1 N sodium hydroxide is required to produce a pink to red colour.	Conforms
Loss on Drying	Not more than 0.5% after drying a sample at 80°C for 2 hours	0.12%
Water	Less than 1.0%	0.8%
Protein and light-absorbing impurities	210 nm ~ 220 nm: Not more than 0.25	0.05
	270 nm ~ 300 nm: Not more than 0.07	0.01
Total Plate Count	Less than 100 CFU/g	< 10 CFU/g



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Yeasts & Moulds	Less than 50 CFU/g	< 10 CFU/g
Escherichia coli	Negative/10g	Not detected
Assay	The chemical name of this product is O-β-D-galactopyranosyl-(1→4)-α-D-glucopyranos anhydrate. The content of C <sub>12</sub> H <sub>22</sub> O <sub>11</sub> should be between 98.0% and 102.0%.	99.9%
Acidity	Taking 1.0 g of this product, and the pH value should be between 4.0 and 7.0.	4.4

**Conclusion:** The testing results of this batch are totally complied with the standard of USP40.