

Certificate of Analysis

Certificate No: C023C210401

Product Name	Trehalose (for injection)	Accordinging	Registered Standard
Batch No.	20210401	Analysis Date	19/04/2021
Sample Origin	Excipient workshop	Report Date	29/04/2021
Packing Spec	10Kg/barrels, 25Kg/barrels	Production Date	18/04/2021
Lot Size	619.78kg	Expiry Date	03/2024
Quantity of Shipment	/	Storage Condition	Keep in a cool, dark and dry place



Items	Specification	Results
[Character]	This product should be a white or off-white crystal powder.	White crystal powder
Specific Rotation	It should be +197°~+201°	+200°
[Identification]	(1) The IR spectrum should be consistent with that of the reference substance. (2) The retention time of the main peak of the test solution shall be the same as that of the reference solution. (3) Molisch reaction (4) Maillard reaction	(1) Compliance (2) Compliance (3) Positive reaction (4) Negative reaction
[Test]		
Acidity	It should be 4.5~6.5.	6.0
Solution Clarity and	A720nm<0.033	-0.0005
Color	A420nm-A720nm<0.067	0.0040
Oxide	≤0.0125%	Compliance
Sulfate	≤0.020%	Compliance
Soluble Starch, Dextrin and Sulfite	It should be negative results	Negative reaction
Water Content	9.0%~11.0%	9.5%
Residue on Ignition	≤0.1%	0.03%
Heavy Metal	≤5ppm	Compliance
Nitrogen	≤0.005%	Compliance



Related Substances	Glucose \leq 0.5%	Not detected
	Maltotriose \leq 0.5%	0.07%
	Other maximum single impurity \leq 0.2%	Not detected
	Total impurities \leq 1%	0.07%
Bacterial Endotoxin	\leq 2.5 IU/g	Compliance
Microbial Limit	Total Aerobic Microbial count: NMT 100CFU/g	Compliance
	Total Yeasts and molds count: NMT 10CFU/g	Compliance
	Escherichia coli: Not detected	Not detected
	Salmonella: Not detected	Not detected
[Assay]	According to the calculation of anhydrous matter, the content of C ₁₂ H ₂₂ O ₁₁ should be 98.0% ~ 101.0%.	99.3%

Conclusion: The above results are in compliance with registered standard.

Rapporteur: 陈林

Director of QC: 戴克金

