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西安普莱特生物工程有限公司

分析报告 Certificate of Analysis

Product Name	D-Mannose		
Batch No.	DM210406	Manufacturing Date	April, 6, 2021
Quantity	1200kg	Expiration Date	April, 5, 2023
Non-Irradiated/Non-ETO/Treat by Heat Only	Solvents		Ethanol and Water

Item	Specification	Result	Method
Assay	98.0%	99.47%	HPLC-ELSD
Appearance	White crystalline powder	Complies	Visual
Odor	Characteristic	Complies	Organoleptic
Identification	Positive	Complies	FTIR
Melting Point	126 – 134 °C	128.0 – 132.0 °C	USP40-NF35<741>
Optical Rotation	+13.3° – +14.3°	+13.7 °	USP40-NF35<781>
Powder Size	95% through 30 mesh	Complies	USP #30 Sieve
Bulk Density	0.30 – 0.50 g/mL	0.49	USP40-NF35<616>
Tapped Density	0.45 – 0.75 g/mL	0.66	USP40-NF35<616>
Solubility	Clear and colorless	Complie	H ₂ O, 10%
Loss on Drying	0.5%	0.08%	USP40-NF35<731>
Residue on Ignition	0.1%	0.05%	USP40-NF35<281>
Pesticide Residues	USP<561>	Complie	USP40-NF35<561>
Total Heavy Metals	10 µg/g	Complies	USP40-NF35<231>
Arsenic (As)	1.0 µg/g	< 0.1	ICP-MS
Cadmium (Cd)	0.5 µg/g	< 0.01	ICP-MS
Lead (Pb)	1.0 µg/g	< 0.1	ICP-MS
Mercury (Hg)	0.5 µg/g	< 0.01	ICP-MS
Total Plate Count	1,000 cfu/g	< 10	USP40-NF35<2021>
Molds and Yeasts	100 cfu/g	< 10	USP40-NF35<2021>
<i>Salmonella</i>	Absence	Complies	USP40-NF35<2022>
<i>E. Coli</i>	Absence	Complies	USP40-NF35<2022>
<i>Staphylococcus aureus</i>	Absence	Complies	USP40-NF35<2022>
Aflatoxins	20 ppb	ND	USP40-NF35<561>
Conclusion	Conform with Specification		
Storage	Store in a well-closed container away from moisture, direct light and heat.		
Packing	25kg/bag Inside: Plastic bag. Outside: Neutral cardboard barrel		