



XI'AN HARMONIOUS NATURAL BIOTECHNOLOGY CO.,LTD

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Certificate of Analysis

Batch No.: HNB220115

Product Name: Meglumine

CAS No.: 6284-40-8

Package: 25Kg/Drum

Manu. Date: 15th, Jan., 2022 Analysis Date: 16th, Jan., 2022 Expiry Date: 14th, Jan., 2024

Storage: Store in an airtight container at a temperature not exceeding 30 °C

Shelf life: 24 Months when properly stored.

ITEMS OF ANALYSIS	SPECIFICATIONS	RESULT
Appearance	White crystalline powder	Complies
Identification	HPLC: Should be consistent with the retention time of Meglumine in the reference product.	Complies
	IR: Should be consistent with the spectrum of the reference product.	Complies
Solubility	Freely soluble in water, slightly soluble in ethanol	Complies
Melting Point	128~132 °C	128~129 °C
Clarity and color of solution	Solution should be clarified	Complies
	Absorbance(420nm) ≤ 0.03%(20%w/v)	0.005
Loss on drying	≤ 1%	0.04%
Residue on ignition	≤ 0.1%	0.02%
Specific optical rotation	-15.7 ° to -17.3 °	-16.4°
Reducing substance	Complies	Complies
Residual solvent	Methanol ≤ 3000ppm	200ppm
Heavy metals	≤ 20ppm	Complies
Assay(on dry basis)	99.0%~100.5%	99.5%
Conclusion	Complies with USP36/BP2010 standard	

QC MANAGER:

王要月

INSPECTOR:

杨思远

ANALYST:

杜静

