

# SHANDONG OCTAGON CHEMICALS LIMITED

## CERTIFICATE OF ANALYSIS

Product name	Amphotericin B (Cas 1397-89-3)		
Batch No.	20191205	Mfg. date	2019.12.11
Rep. Date	2019.12.18	Exp. date	2021.12.10
Packaging	0.5kg/Tin	Batch Quantity	7.98KG
Test Items	Standards: USP36		Results
Appearance	Yellow to orange powder, no visible evidence of contamination by foreign mater		Yellow powder
Identification	Should conform		Conforms
Loss on drying	NMT5.0%		3.0%
Absorbance ration	362/381=0.57~0.61 381/405=0.87~0.93		0.60 0.87
Residue on ignition	NMT0.5%		0.01%
Solubility	Should conform		Conforms
Limit of amphotericin A	NMT5%		ND
Assay(Microbial)	NLT840µg/mg calculated on dried basis		1052µg/mg
Assay(HPLC)	NLT90% on dried basis		103%
Microbial limits	Should conform		conforms
Bacterial endotoxins	NMT1EU/mg		<1EU/mg
Residual solvents	Ethanol: NMT5000ppm		600ppm
	DMF: NMT6000ppm		ND
	Acetone:NMT5000ppm		1580ppm
Conclusion	It meets the requirements of USP36 Standards		
Storage	Store in a well-closed container at ambient temperature		
Prepared by: LI	Reviewed by: WEI	Released by:Zhang	