SHANDONG OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	Amphotericin B Lipisomal		
Batch No.	2206204	Mfg. Date	2022.06.24
Rep. Date	2022.07.14	Exp. date	2025.06.23
Packaging	1kg/Tin	Batch Quantity	8.45KG
Test Items	Standards: USP42		Results
Appearance	Yellow to orange powder, no visible evidence of contamination by foreign mater		Yellow powder
Identification	IR/HPLC		Conforms
Related Substances	Impurity A at 303nm: NMT2.0% Any other impurity at 303nm: NMT1.0% Impurity B at 383nm: NMT4.0% Impurity C at 383nm: NMT2.0% Impurity with RRT 1.41 at 383nm: NMT2.0% Any other impurity at 383nm: NMT1.0% Total impurities at 303 and 383nm: NMT15.0%		
Loss on drying	NMT5.0%		2.4%
Sulphated ash	NMT0.5%		0.04%
Bacterial endotoxins	NMT1EU/mg		<1EU/mg
Assay(Microbial)	NLT840μg/mg calculated on dried basis		1115μg/mg
Assay(HPLC)	NLT90% on dried basis		122%
Microbial limits	Total aerobic counts: NMT100cfu/G E. Coli: Negative Salmonella: Negative Staphylococcus aureus: Negative Pseudomonas aeruginosa: Negative		ND ND ND ND ND
Residual Solvents	Ethanol: NMT5000ppm DMF: NMT4000ppm Acetone: NMT5000ppm Triethylamine: NMT2000ppm		1909ppm 2713ppm 781ppm ND
Conclusion	It meets the requirements of USP42 Standards		
Storage	Store in a well-closed container at ambient temperature		
Prepared by: LI	Reviewed by: WEI		Released by:Zhang

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