山东八方化工科技有限公司
SHANDONG OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	Cyclosporine (Cas 59865-13-3)		
Batch No.	HNCN2404401U	Mfg. Date	2024.04.04
Rep. Date	2024.04.29	Retest Date	2027.04.03
Packaging	500G/Bag/Tin/Carton	Batch Quantity	53.19KG
Test Items	Standards: Current USP		Results
Appearance	White to almost white powder		White powder
Identification	Infrared spectroscopy		Conforms
	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay		Conforms
Related substances	Total impurities: NMT 1.5%		0.6%
	Any individual impurity: NMT 0.7%		0.3%
Residual solvent	Ethanol: NMT 5000ppm		ND
	Acetone: NMT 5000ppm		ND
	Ethyl acetate: NMT 5000ppm		71ppm
Loss on drying	NMT 2.0%		0.1%
Assay(on dried basis)	97.0%~101.5%		98.9%
Microbial limits	TAMC: NMT 10^3 cfu/g		<20 cfu/g
	TYMC: NMT 10^2 cfu/g		<20 cfu/g
Conclusion	It meets the requirements of current USP		
Storage	Preserve in well-closed, light resistant containers.		
Reporter: LI			Reviewed By: WEI

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