SHANDONG OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	**Cyclosporine (Cas 59865-13-3)**		
Batch No.	2211533	Mfg. date	2022.11.07
Rep. Date	2022.11.17	Exp. date	2026.11
Packaging	5kg/Tin	Batch Size	15.31KG
Test Items	Standards: USP43		Results
Appearance	White to almost white powder		White powder
Identification	HPLC:Should conform		Conforms
Loss on drying	NMT2.0%		0.4%
Heavy metals	NMT20ppm		<20ppm
Related substances	Individual impurity:NMT0.7%		0.5%
	Total impurities:NMT1.5%		1.2%
	Other unknown impurity:NMT0.1%		<0.1%
Microbial Limits	TAMC: NMT1000cfu/g TYMC: NMT100cfu/g		40cfu/g <10cfu/g
Residual solvents	Acetone: NMT0.5% Ethyl acetate: NMT0.5%		0.2% ND
Assay	97.0%~101.5%		99.0%
Conclusion	It meets the requirements of USP43 Standards		
Storage	Store in an air-tight container at ambient temperature		
Prepared by: LI	Reviewed by: WEI		Released by:Zhang

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