

OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	Cyclosporine (Cas 59865-13-3)		
Batch No.	20191003	Mfg. date	2019.10.05
Rep. Date	2019.10.08	Exp. date	2021.10.04
Packaging	25kg/drum	Batch Size	58.9KG
Test Items	Standards: USP41		Results
Appearance	White to almost white powder		White powder
Identification	HPLC:Should conform		Conforms
Loss on drying	NMT2.0%		0.11%
Heavy metals	NMT20ppm		<20ppm
Related substances	Individual impurity:NMT0.7%		0.29%
	Total impurities:NMT1.5%		0.58%
	Other unknown impurity:NMT0.1%		<0.1%
Residual solvents	Ethanol: NMT5000ppm Acetone: NMT5000ppm Ethyl Acetate: NMT5000ppm		ND ND ND
Microbial Limits	TAMC: NMT1000cfu/g TYMC: NMT100cfu/g		Conforms
Assay	97.0%~101.5%		98.9%
Conclusion	It meets the requirements of USP41 Standards		
Storage	Store in a well-closed container at ambient temperature		
Prepared by: LI	Reviewed by: WEI	Released by:Zhang	