



CERTIFICATE OF ANALYSIS

Product name	Cyclosporine (Cas 59865-13-3)		
Batch No.	20201201	Mfg. date	2020.12.15
Rep. Date	2021.12.24	Exp. date	2022.12.14
Packaging	25kg/drum	Batch Size	29.7KG
Test Items	Standards: USP41		Results
Appearance	White to almost white powder		White powder
Identification	HPLC:Should conform		Conforms
Loss on drying	NMT2.0%		0.10%
Heavy metals	NMT20ppm		<20ppm
Related substances	Individual impurity:NMT0.7%		0.27%
	Total impurities:NMT1.5%		0.56%
	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%		99.3%
Conclusion	It meets the requirements of USP41 Standards		
Storage	Store in a well-closed container at ambient temperature		
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