

CERTIFICATE OF ANALYSIS

Product Name:	Clindamycin hydrochloride		
Batch No.	20230330212	Packing	25kg/drum
Manufacturing Date	March 30, 2023	Expiry Date TO	March 29, 2027
According To	USP43	Quality	426.7kg
Analysis Date	April 13, 2023		
Analytical results			
Items	Specifications		Results
Characteristics	A white or almost white crystalline powder		White crystalline powder
Identification	A: The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay		Conform
	B. Infrared Absorption		Conform
Crystallinity	Meets the requirements		Conform
Acidity	pH 3.0~5.5		4.3
Water	3.0%~6.0%		3.60%
Residue on ignition	≤0.5%		0.09%
Bulk density	/		0.47g/cm ³
Tapped density	/		0.67g/cm ³
Related compounds	clindamycin B ≤2.0%		1.10%
	7-epiclindamycin ≤4.0%		0.48%
	other individual related compound ≤1.0%		0.16%
	total of all related compounds ≤6.0%		2.10%
	Ethanol ≤0.5%		none detected
Residual solvents	Acetone ≤0.5%		0.015%
	Chloroform ≤0.006%		none detected
	N.N-Dimethylformamide ≤0.088%		none detected
Assay	not less than 800ug per mg		859μg/mg
Conclusion	This product conforms to the standard.		

Inspector: Carlifor Wu

Verifier: Jack He