

Lot: 031112



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CERTIFICATE OF ANALYSIS

Report No. 12-0055Name of product Clindamycin HydrochlorideMaterial No. 04003DBatch No. 120609X8Quantity 223.10KgPackage 25Kg/DrumMfg Date 2012-06-05Report Date 2012-06-10Retest Date 2015-06-05

Items	Specification	Results
Characters	White or almost white crystalline powder	White crystalline powder
Solubility	Very soluble in water, slightly soluble in alcohol.	Conform
Identification	A. IR Conform	Conform
	D. Chlorides reaction Conform	Conform
Specific optical rotation	+135°~+150°	+143°
pH	3.0~5.0	3.8
Related Substances	Clindamycin B ≤2.0%	0.57%
	7-epiclindamycin ≤4.0%	0.94%
	Any other impurity ≤1.0%	0.21%
	Total of impurity ≤6.0%	2.2%
Residual solvents	Acetone ≤5000ppm	164ppm
	Ethanol ≤5000ppm	No detected
	N,N-Dimethylformamide ≤880ppm	No detected
	Chloroform ≤60ppm	No detected
Water	3.0~6.0%	4.1%
Sulphated ash	≤0.5%	0.06%
Assay	Anhydrous substance, 91.0~102.0% $C_{18}H_{34}Cl_2N_2O_5S$	98.6%
Conclusion	Complies with EP7.0	

QC 陆明

QA 陆明