

Lot: 0100720

Report No.: COA-KL-EP10-11

NO.588,FENGZE ROAD, TIANTAI, ZHEJIANG

317200, CHINA



ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Name of product Clindamycin HydrochlorideMaterial No. 04101BBatch No. K-200516BQuantity 220.42KgPackage 25Kg/DrumMfg Date 2020-05-21Report Date 2020-07-01Retest Date 2023-05-21

Items		Specification	Results
Characters	Appearance	White or almost white crystalline powder	White crystalline powder
	Solubility	Very soluble in water, slightly soluble in ethanol (96%).	Conform
pH by pH meter		3.0~5.0	4.2
Identification		A. IR spectrum conforms to RS	Conform
		D. Chlorides reaction	Conform
Water by KF		3.0~6.0%	4.0%
Specific optical rotation		+135°~+150°	+143°
Sulphated ash		≤0.5%	0.02%
Related substances by HPLC		Impurity A (Lincomycin) ≤0.5%	0.19%
		Impurity B (Clindamycin B) ≤2.0%	0.48%
		Impurity C (7-epiclindamycin) ≤4.0%	0.81%
		RRT0.36 ≤0.5%	0.088%
		RRT0.71 ≤0.5%	0.14%
		RRT0.87 ≤0.5%	0.14%
		Any other impurity ≤0.10%(each)	N.D.
		Total Related substances ≤6.0%	1.8%
Assay by HPLC		92.0~102.0% (on anhydrous basis)	97.8%
Residual solvents by GC		Ethanol ≤5000ppm	N.D.
		Acetone ≤5000ppm	89ppm
		Chloroform ≤60ppm	N.D.
Conclusion		Complies EP10	

QC 17-4

QA 31. AS 19