

Gte: 0241216



ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

Report No. :COA-KL-EP8.0-14

NO.588,FENGZE ROAD,TIANTAI,ZHEJIANG

317200,CHINA

ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Name of product Clindamycin HydrochlorideMaterial No. 04101BBatch No. 161019BQuantity 223.00KgPackage 25Kg/DrumMfg Date 2016-10-22Report Date 2016-11-30Retest Date 2019-10-22

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
Identification		A. IR spectrum conforms to RS	Conform
		D. Chlorides reaction	Conform
Specific optical rotation		+135° ~ +150°	+144°
pH		3.0~5.0	4.3
Water		3.0~6.0%	3.9%
Sulphated ash		≤0.5%	0.05%
Residual solvents		Acetone ≤5000ppm	116ppm
		Ethanol ≤5000ppm	No detected
		Chloroform ≤60ppm	No detected
Related Substances (HPLC)		Lincomycin ≤1.0%	0.19%
		Clindamycin B ≤2.0%	0.63%
		7-epiclindamycin ≤4.0%	0.87%
		RRT0.36 ≤0.5%	0.10%
		RRT0.71 ≤0.5%	0.12%
		RRT0.87 ≤0.5%	0.15%
		Any other impurity ≤0.10%(each)	No detected
		Total Related substances ≤6.0%	2.1%
Assay		91.0~102.0% $C_{18}H_{34}Cl_2N_2O_5S$ (on the anhydrous basis)	98.1%
Conclusion		Complies EP8.0	

QC 张丽梅

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