



ZHEJIANG Tiantai PHARMACEUTICAL CO., LTD.

Report No. :COA-KL-EP9.3-27

NO.588,FENGZE ROAD,TIANTAI,ZHEJIANG

317200,CHINA

ZHEJIANG Tiantai PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Name of product Clindamycin HydrochlorideMaterial No. 04101BBatch No. K-190420BQuantity 223.48KgPackage 25Kg/DrumMfg Date 2019-04-15Report Date 2019-05-29Retest Date 2022-04-15

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%	4.1%
Specific optical rotation		+135° ~ +150°	+144°
Sulphated ash		≤0.5%	0.06%
Related substances by HPLC		Impurity A (Lincomycin) ≤0.5%	0.16%
		Impurity B (Clindamycin B) ≤2.0%	0.54%
		Impurity C (7-epiclindamycin) ≤4.0%	0.81%
		RRT0.36 ≤0.5%	0.078%
		RRT0.71 ≤0.5%	0.20%
		RRT0.87 ≤0.5%	0.18%
		Any other impurity ≤0.10%(each)	N.D.
		Total Related substances ≤6.0%	2.0%
Assay by HPLC		92.0~102.0% (on anhydrous basis)	98.3%
Residual solvents by GC		Ethanol ≤5000ppm	N.D.
		Acetone ≤5000ppm	164ppm
		Chloroform ≤60ppm	N.D.
Conclusion		Complies EP9.3	

QC 叶平

QA 陈松