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ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

Report No. :COA-KL-EP9.3-14

NO.588,FENGZE ROAD,TIAN TAI,ZHEJIANG

317200,CHINA

ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Name of product Clindamycin Hydrochloride

Material No. 04101B

Batch No. K-171105B

Quantity 222.40Kg

Package 25Kg/Drum

Mfg Date 2017-11-22

Report Date 2018-02-27

Retest Date 2020-11-22

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°	+143°
pH by pH meter		3.0~5.0	4.2
Water by KF		3.0~6.0%	3.9%
Sulphated ash		≤0.5%	0.08%
Residual solvents by GC		Acetone ≤5000ppm	156ppm
		Ethanol ≤5000ppm	No detected
		Chloroform ≤60ppm	No detected
Related substances by HPLC		Impurity A (Lincomycin) ≤0.5%	0.14%
		Impurity B (Clindamycin B) ≤2.0%	0.48%
		Impurity C (7-epiclindamycin) ≤4.0%	0.67%
		RRT0.36 ≤0.5%	0.10%
		RRT0.71 ≤0.5%	0.054%
		RRT0.87 ≤0.5%	0.14%
		Any other impurity ≤0.10%(each)	No detected
Total Related substances		≤6.0%	1.6%
Assay by HPLC		92.0~102.0% (on anhydrous basis)	98.3%
Conclusion		Complies EP9.3	

QC 杨小

QA 杨燕