



ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS



Report No. 14-0017

Name of product Clindamycin Hydrochloride

Material No. 04101B

Batch No. 140201B

Quantity 220.60Kg

Package 25Kg/Drum

Mfg Date 2014-02-17

Report Date 2014-02-26

Retest Date 2017-02-17

Items		Specification	Results
Characters	Appearance	White or almost white crystalline powder	White crystalline powder
	Solubility	Very soluble in water, slightly soluble in ethanol (96 percent)	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%	3.8%
Sulphated ash		≤0.5%	0.06%
Residual solvents		Acetone ≤5000ppm	106ppm
		Ethanol ≤5000ppm	No detected
		N,N-Dimethylformamide ≤880ppm	No detected
		Chloroform ≤60ppm	No detected
Related Substances(HPLC)		Lincomycin ≤1.0%	0.20%
		Clindamycin B ≤2.0%	0.56%
		7-epiclindamycin ≤4.0%	0.85%
		RRT0.36 ≤0.5%	0.12%
		RRT0.71 ≤0.5%	0.20%
		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 ₂ N ₂ O ₅ S (on the anhydrous basis)	97.9%
Conclusion		Complies EP8.0	

QC

QA