



ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

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ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Report No. 12-0006

Name of product Clindamycin Hydrochloride

Material No. 04003A

Batch No. 120402X5

Quantity 150.00Kg

Package 25Kg/Drum

Mfg Date 2012-04-13

Report Date 2012-06-18

Retest Date 2015-04-13

Items	Specification	Results
Characters	White or almost white crystalline powder	White crystalline powder
Solubility	Very soluble in water, slightly soluble in alcohol.	Conform
Identification	A. IR Conform	Conform
	D. Chlorides reaction Conform	Conform
Specific optical rotation	+135°~+150°	+143°
pH	3.0~5.0	3.9
Related Substances	Clindamycin B ≤2.0%	0.83%
	7-epiclindamycin ≤4.0%	0.81%
	Any other impurity ≤1.0%	0.28%
	Total of impurity ≤6.0%	2.5%
Residual solvents	Acetone ≤5000ppm	82ppm
	Ethanol ≤5000ppm	No detected
	N,N-Dimethylformamide ≤880ppm	No detected
	Chloroform ≤60ppm	No detected
Water	3.0~6.0%	4.2%
Sulphated ash	≤0.5%	0.07%
Assay	Anhydrous substance, 91.0~102.0% C ₁₈ H ₃₄ Cl ₂ N ₂ O ₅ S	98.5%
Conclusion	Complies with EP7.0	

QC 11/11/13

QA 11/11/13