



ZHEJIANG Tiantai PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS



Report No. 13-0018

Name of product Clindamycin Hydrochloride

Material No. 04003D

Batch No. 130709X8

Quantity 189.94Kg

Package 25Kg/Drum

Mfg Date 2013-07-06

Report Date 2013-11-27

Retest Date 2016-07-06

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	4.0
Related Substances	Clindamycin B ≤2.0%	0.66%
	7-epiclindamycin ≤4.0%	0.91%
	Any other impurity ≤1.0%	0.20%
	Total of impurity ≤6.0%	2.2%
Residual solvents	Acetone ≤5000ppm	180ppm
	Ethanol ≤5000ppm	No detected
	N,N-Dimethyl formamide ≤880ppm	No detected
	Chloroform ≤60ppm	No detected
Water	3.0~6.0%	4.1%
Sulphated ash	≤0.5%	0.05%
Assay	Anhydrous substance, 91.0~102.0% C ₁₈ H ₃₄ Cl ₂ N ₂ O ₅ S	98.9%
Conclusion	Complies with EP7.0	

QC

QA