

Lote: 0050415



ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Report No. 15-0025

Name of product Clindamycin Hydrochloride

Material No. 04101C

Batch No. 141021C

Quantity 220.10Kg

Package 25Kg/Drum

Mfg Date 2014-10-14

Report Date 2015-01-22

Retest Date 2017-10-14

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	4.3
Related Substances	Clindamycin B ≤2.0%	0.62%
	7-epiclindamycin ≤4.0%	0.93%
	Any other impurity ≤1.0%	0.26%
	Total of impurity ≤6.0%	2.3%
Residual solvents	Acetone ≤5000ppm	164ppm
	Ethanol ≤5000ppm	No detected
	Chloroform ≤60ppm	No detected
Water	3.0-6.0%	3.9%
Sulphated ash	≤0.5%	0.03%
Assay	Anhydrous substance, 91.0-102.0% $C_{18}H_{34}ClN_2O_5S$	97.5%
Conclusion	Complies with EP8.0	

QC

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