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ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

Report No. :COA-KL-EP9.3-27

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-180408B

Quantity 223.88Kg

Package 25Kg/Drum

Mfg Date 2018-04-16

Report Date 2018-05-24

Retest Date 2021-04-16

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
pH by pH meter		3.0~5.0	4.2
Identification	A. IR spectrum conforms to RS		Conform
	D. Chlorides reaction		Conform
Water by KF		3.0~6.0%	3.9%
Specific optical rotation		+135° ~ +150°	+144°
Sulphated ash		≤0.5%	0.05%
Related substances by HPLC	Impurity A (Lincomycin)	≤0.5%	0.13%
	Impurity B (Clindamycin B)	≤2.0%	0.58%
	Impurity C (7-epiclindamycin)	≤4.0%	0.67%
	RRT0.36	≤0.5%	0.10%
	RRT0.71	≤0.5%	0.076%
	RRT0.87	≤0.5%	0.16%
	Any other impurity	≤0.10%(each)	N.D.
	Total Related substances	≤6.0%	1.7%
Assay by HPLC		92.0~102.0% (on anhydrous basis)	98.0%
Residual solvents by GC	Ethanol	≤5000ppm	N.D.
	Acetone	≤5000ppm	179ppm
	Chloroform	≤60ppm	N.D.
Conclusion		Complies EP9.3	

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