

ZHEJIANG Tiantai Pharmaceutical Co., Ltd.

Report No.: COA-KL-EP9-14

NO.588,FENGZE ROAD,TIANTAI,ZHEJIANG

317200,CHINA

ZHEJIANG Tiantai Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Name of product Clindamycin Hydrochloride
Batch No. K-171217B
Package 25Kg/Drum
Report Date 2018-01-04

Material No. 04101B
Quantity 221.70Kg
Mfg Date 2017-12-23
Retest Date 2020-12-23

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
Identification	A. IR spectrum conforms to RS		Conform
	D. Chlorides reaction		Conform
Specific optical rotation		+135° ~ +150°	+145°
pH		3.0-5.0	4.2
Water		3.0-6.0%	3.8%
Sulphated ash		≤0.5%	0.04%
Residual solvents	Acetone	≤5000ppm	192ppm
	Ethanol	≤5000ppm	No detected
	Chloroform	≤60ppm	No detected
Related Substances (HPLC)	Lincomycin	≤1.0%	0.22%
	Clindamycin B	≤2.0%	0.55%
	7-epiclindamycin	≤4.0%	0.71%
	RRT0.36	≤0.5%	0.16%
	RRT0.71	≤0.5%	0.059%
	RRT0.87	≤0.5%	0.16%
	Any other impurity	≤0.10%(each)	No detected
	Total Related substances	≤6.0%	1.9%
Assay		91.0-102.0% $C_{18}H_{34}Cl_2N_2O_5S$ (on the anhydrous basis)	97.9%
Conclusion		Complies EP9	

QC *mx-y*

QA *z*

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

18A18-008

Director Técnico