

ZHEJIANG Tiantai PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Name of product Clindamycin Hydrochloride Material No. 04101B
Batch No. K-211002B Quantity 220.60Kg
Package 25Kg/Drum Mfg Date 2021-10-07
Report Date 2021-10-22 Retest Date 2024-10-07

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	4.3
Identification		A. IR spectrum conforms to RS	Conform
		D. Chlorides reaction	Conform
Water by KF		3.0~6.0%	4.0%
Specific optical rotation		+135°~ +150°	+143°
Sulphated ash		≤0.5%	0.03%
Related substances by HPLC		Impurity A (Lincomycin) ≤0.5%	0.25%
		Impurity B (Clindamycin B) ≤2.0%	0.53%
		Impurity C (7-epiclindamycin) ≤4.0%	0.74%
		RRT0.36 ≤0.5%	0.077%
		RRT0.71 ≤0.5%	0.19%
		RRT0.87 ≤0.5%	0.16%
		Any other impurity ≤0.10%(each)	N.D.
		Total Related substances ≤6.0%	1.9%
Assay by HPLC		92.0~102.0% (on anhydrous basis)	98.5%
Residual solvents by GC		Ethanol ≤5000ppm	N.D.
		Acetone ≤5000ppm	160ppm
		Chloroform ≤60ppm	N.D.
Conclusion		Complies EP10	

QC *h7-11*

QA *3/21/24*

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