

METAPHARMACEUTICAL

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Report No.: COA-KL-EP11-00

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ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

质控中心

Name of Product	Clindamycin Hydrochloride	Material No.	04101F
Batch No.	K-240335F	Quantity	220.62Kg
Package	25Kg/Drum	Mfg. Date	2024-03-30
Report Date	2024-07-18	Retest Date	2027-03-30
Items	Specification		Results
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
pH by pH meter	3.0~5.0		4.3
Specific optical rotation	+135°~ +150°		+143°
Related substances by HPLC	Impurity B (Clindamycin B)	≤2.0%	0.53%
	Impurity C (7-epiclindamycin)	≤4.0%	0.53%
	Any other impurity	≤0.5%	0.14%
	Total Related substances	≤6.0%	1.5%
Residual solvents by GC	Ethanol	≤5000ppm	N.D.
	Acetone	≤5000ppm	130ppm
	Chloroform	≤60ppm	N.D.
Water by KF	3.0~6.0%		4.0%
Sulfated ash	≤0.5%		0.053%
Assay by HPLC	92.0~102.0% (On anhydrous basis)		98.48%
Conclusion	Complies with EP11		

QC

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