

METAPHARMACEUTICAL

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14/03/2023

Report No.: COA-KL-EP11-00

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ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Name of Product	Clindamycin Hydrochloride	Material No.	04101F
Batch No.	K-230101F	Quantity	219.04Kg
Package	25Kg/Drum	Mfg. Date	2023-01-01
Report Date	2023-02-23	Retest Date	2026-01-01
Items	Specification	Results	
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°	+144°	
Sulfated ash	≤0.5%	0.034%	
Related substances by HPLC	Impurity B (Clindamycin B)	≤2.0%	0.16%
	Impurity C (7-epiclindamycin)	≤4.0%	0.65%
	Any other impurity	≤0.5%	0.15%
	Total Related substances	≤6.0%	1.1%
Assay by HPLC	92.0~102.0% (On anhydrous basis)	99.1%	
Residual solvents by GC	Ethanol	≤5000ppm	N.D.
	Acetone	≤5000ppm	138ppm
	Chloroform	≤60ppm	N.D.
Conclusion	Complies with EP11		

QC 徐亚芳

QA 陈明