

METAPHARMACEUTICAL

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08/04/2024

Report No.: COA-KL-EP11-00

Add: 588# Fengze RD, Tiantai, Zhejiang, China

Tel:0086-0576-83993512 Post Code:317200



ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS



Name of Product	Clindamycin Hydrochloride	Material No.	04101B
Batch No.	K-230506B	Quantity	218.94Kg
Package	25Kg/Drum	Mfg. Date	2023-05-03
Report Date	2023-12-13	Retest Date	2026-05-03
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	4.2	
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°	+143°	
Sulfated ash	≤0.5%	0.042%	
Related substances by HPLC	Impurity B (Clindamycin B)	≤2.0%	0.62%
	Impurity C (7-epiclindamycin)	≤4.0%	0.80%
	Any other impurity	≤0.5%	0.34%
	Total Related substances	≤6.0%	2.1%
Assay by HPLC	92.0~102.0% (On anhydrous basis)	97.7%	
Residual solvents by GC	Ethanol	≤5000ppm	N.D.
	Acetone	≤5000ppm	120ppm
	Chloroform	≤60ppm	N.D.
Conclusion	Complies with EP11		

QC 徐晓

QA 张丽梅