

METAPHARMACEUTICAL

N DE LOTE:

0091025

Miguel

08/10/2025



ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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.

CERTIFICATE OF ANALYSIS

Name of Product	Clindamycin Hydrochloride	Material No.	04101F
Batch No.	K-250820F	Quantity	220.82Kg
Package	25Kg/Drum	Mfg. Date	2025-08-21
Report Date	2025-09-19	Retest Date	2028-08-21
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		4.2
Specific optical rotation	+135°~+150°		+143°
Related substances by HPLC	Impurity B (Clindamycin B)	≤2.0%	0.10%
	Impurity C (7-epiclindamycin)	≤4.0%	0.49%
	Any other impurity	≤0.5%	0.28%
	Total Related substances	≤6.0%	1.0%
Residual solvents by GC	Ethanol	≤5000ppm	N.D.
	Acetone	≤5000ppm	323ppm
	Chloroform	≤60ppm	N.D.
Water by KF	3.0~6.0%		4.0%
Sulfated ash	≤0.5%		0.030%
Assay by HPLC	92.0~102.0% (On anhydrous basis)		98.2%
Conclusion	Complies with EP11		

QC

10/10/25

QA

10/10/25