

METAPHARMACEUTICAL

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16/06/2025

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.	04101B
Batch No.	K-241111B	Quantity	223.06Kg
Package	25Kg/Drum	Mfg. Date	2024-11-25
Report Date	2025-05-08	Retest Date	2027-11-25
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		4.4
Specific optical rotation	+135°~ +150°		+144°
Related substances by HPLC	Impurity B (Clindamycin B)	≤2.0%	0.082%
	Impurity C (7-epiclindamycin)	≤4.0%	0.72%
	Any other impurity	≤0.5%	0.10%
	Total Related substances	≤6.0%	0.98%
Residual solvents by GC	Ethanol	≤5000ppm	N.D.
	Acetone	≤5000ppm	236ppm
	Chloroform	≤60ppm	N.D.
Water by KF	3.0~6.0%		3.9%
Sulfated ash	≤0.5%		0.043%
Assay by HPLC	92.0~102.0% (On anhydrous basis)		98.9%
Conclusion	Complies with EP11		

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