



ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Report No. 12-0019

Name of product Clindamycin Phosphate

Material No. 04007D

Batch No. M121201X10

Quantity 200.00Kg

Package 25Kg/Drum

Mfg Date 2012-10-09

Report Date 2012-12-10

Retest Date 2015-10-09

Items	Specification	Results
Appearance	White or almost white powder	White powder
Identification	A. IR: consistent with the spectrum obtained with clindamycin phosphate CRS D. The filtrate gives reaction of phosphates	Conform
Appearance of the solution	Clear and colourless	Clear and colourless
pH	3.5~4.5	4.0
Specific optical rotation	+115°~+130°	+121°
Related Substances	Lincomycin-2-phosphate ≤0.5% Lincomycin ≤0.5% Clindamycin B phosphate ≤2.5% Clindamycin Pyrophosphate ≤0.5% Dehydroclindamycin phosphate ≤0.5% 7-Epiclindamycin phosphate ≤1.2% Clindamycin ≤0.8% Individual unknown impurity ≤0.2% Total unknown impurities ≤0.5% Total impurities ≤4.0%	0.14% No detected 0.48% No detected 0.15% 0.46% No detected No detected No detected 1.2%
Water	≤6.0%	0.37%
Residual solvents	Ethanol ≤5000ppm Acetone ≤5000 ppm Methanol ≤3000 ppm Chloroform ≤60ppm Pyridine ≤200 ppm N,N-dimethylformamide ≤880 ppm	486ppm No detected No detected No detected No detected No detected
Bacterial endotoxins	≤0.6 IU/mg	≤0.3 IU/mg
Assay	95.0~102.0%	99.3%
Conclusion	Complies with EP7.0	

QC

QA