



ZHEJIANG Tiantai PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Report No. 12-0017

Name of product Clindamycin PhosphateMaterial No. 04007DBatch No. 121001X10Quantity 323.70KgPackage 25Kg/DrumMfg Date 2012-10-09Report Date 2012-10-15Retest 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	3.9
Specific optical rotation	+115°~+130°	+122°
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%	0.11% No detected 0.60% No detected 0.19% 0.49% No detected No detected No detected 1.4%
Water	≤6.0%	0.33%
Residual solvents	Ethanol ≤5000ppm Acetone ≤5000 ppm Methanol ≤3000 ppm Chloroform ≤60ppm Pyridine ≤200 ppm N,N-dimethylformamide ≤880 ppm	762ppm 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%	97.8%
Conclusion	Complies with EP7.0	

QC 1418

QA 陆永强