



ZHEJIANG Tiantai PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Report No. 14-0002

Name of product Clindamycin PhosphateMaterial No. 04102BBatch No. 140401BQuantity 324.10KgPackage 25Kg/DrumMfg Date 2014-04-06Report Date 2014-04-14Retest Date 2017-04-06

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°	+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%	0.089% No detected 0.45% 0.074% 0.19% 0.51% No detected No detected No detected 1.3%
Water	≤6.0%	0.37%
Residual solvents	Ethanol ≤5000ppm Acetone ≤5000ppm Methanol ≤3000ppm Chloroform ≤60ppm	1252ppm No detected No detected No detected
Bacterial endotoxins	<0.6 IU/mg	<0.3 IU/mg
Assay	95.0~102.0%	98.9%
Conclusion	Complies with EP8.0	

QC

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