



ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Report No. 13-0005

Name of product Clindamycin Phosphate

Material No. 04102B

Batch No. 131202B

Quantity 329.90Kg

Package 25Kg/Drum

Mfg Date 2013-12-09

Report Date 2013-12-16

Retest Date 2016-12-09

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%	0.12% No detected 0.60% 0.078% 0.21% 0.50% No detected No detected No detected 1.5%
Water	≤6.0%	0.47%
Residual solvents	Ethanol ≤5000ppm Acetone ≤5000 ppm Methanol ≤3000 ppm Chloroform ≤60ppm Pyridine ≤200 ppm N,N-dimethyl formamide ≤880 ppm	1213ppm 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%	99.9%
Conclusion	Complies with EP7.0	

QC 王明

QA 陈美玲