



ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Report No. 14-0010

Name of product Clindamycin Phosphate

Material No. 04102B

Batch No. 140801B

Quantity 323.50Kg

Package 25Kg/Drum

Mfg Date 2014-08-09

Report Date 2014-08-25

Retest Date 2017-08-09

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°	+122°
Related Substances	Lincomycin-2-phosphate ≤0.5%	0.13%
	Lincomycin ≤0.5%	No detected
	Clindamycin B phosphate ≤2.5%	0.49%
	Clindamycin Pyrophosphate ≤0.5%	0.097%
	Dehydroclindamycin phosphate ≤0.5%	0.12%
	7-Epiclindamycin phosphate ≤1.2%	0.48%
	Clindamycin ≤0.8%	No detected
	Individual unknown impurity ≤0.2%	No detected
	Total unknown impurities ≤0.5%	No detected
Water	Total impurities ≤4.0%	1.3%
	≤6.0%	0.57%
Residual solvents	Ethanol ≤5000ppm	1351ppm
	Acetone ≤5000ppm	No detected
	Methanol ≤3000ppm	No detected
	Chloroform ≤60ppm	No detected
Bacterial endotoxins	<0.6 IU/mg	<0.3 IU/mg
Assay	95.0~102.0%	99.9%
Conclusion	Complies with EP8.0	

QC

QA