



ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Report No. 14-0004

Name of product Clindamycin Phosphate

Material No. 04102B

Batch No. M140401B

Quantity 200.00Kg

Package 25Kg/Drum

Mfg Date 2013-11-06

Report Date 2014-04-14

Retest Date 2016-11-06

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	3.9
Specific optical rotation	+115°~+130°	+123°
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%
Water	Total impurities	≤4.0%
		1.3%
Water	≤6.0%	0.39%
Residual solvents	Ethanol	≤5000ppm
	Acetone	≤5000ppm
	Methanol	≤3000ppm
	Chloroform	≤60ppm
Bacterial endotoxins	<0.6 IU/mg	<0.3 IU/mg
Assay	95.0~102.0%	98.8%
Conclusion	Complies with EP8.0	

QC

QA