

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT</u>
Appearance	White or almost white crystalline powder	White crystalline powder
Identification		
IR	IR spectrum should correspond to that of the reference standard	Conform
Crystallinity	Should meet the requirement	Conform
pH	3.5~4.5	3.8
Water	NMT 6.0%	1.0%
Related substances		
Lincomycin phosphate	NMT 1.0%	0.3%
Lincomycin	NMT 0.5%	ND
Clindamycin B phosphate	NMT 1.5%	0.4%
7-Epiclindamycin phosphate	NMT 0.8%	0.05%
Clindamycin 3- phosphate	NMT 0.3%	0.02%
Clindamycin	NMT 0.5%	ND
Individual unknown impurity	NMT 1.0%	0.2%
Total impurities	NMT 4.0%	1.3%
Residual Solvents		
Ethanol	NMT 5000ppm	156ppm
Acetone	NMT 5000ppm	ND
Toluene	NMT 890ppm	ND
Pyridine	NMT 200ppm	ND
Bacterial Endotoxins	NMT 0.58EU/mg	Conform
Assay(On anhydrous basis)	NLT 758µg/mg	825µg/mg