

XINYU PHARMACEUTICAL CO.,LTD.

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CERTIFICATE OF ANALYSIS

Product name: Clindamycin Phosphate	Batch No.: P2105016A
Report No.: C-110034-21-0028	Analysis Date: 2021.5.24
Manufacture Date: 2021.5.19	Retest Date: 2023.4
Analysis Standard: CURRENT USP	Quantity: 340.38Kg

Analytical Test	Specifications	Results
Characteristics	White to off-white Powder	White Powder
Identification	Conform to requirements	Pass
Crystallinity	Conforms to requirements	Pass
pH	3.5~4.5	3.8
Water by KF	≤6.0%	0.4%
Impurities by HPLC:		
Individual Impurities		
RRT 0.36(Lincomycin Phosphate)	≤1.0%	0.14%
RRT 0.50(Lincomycin)	≤0.5%	none detected
RRT 0.77(Clindamycin B Phosphate)	≤1.5%	0.15%
RRT 0.89(7-Epiclindamycin Phosphate)	≤0.8%	0.13%
RRT 0.93 (Clindamycin3 Phosphate)	≤0.3%	0.06%
RRT 1.4(Clindamycin)	≤0.5%	none detected
Single Largest Unknown:	≤0.50%	0.06%
Total Impurities:	≤2.0%	0.61%
Residual Solvents by GC:		
DMF	≤400ppm	none detected
Methanol:	≤1500ppm	none detected
Ethanol	≤3000ppm	48ppm
Acetone:	≤2000ppm	none detected
Chloroform	≤60ppm	none detected
Pyridine	≤100ppm	none detected
Total aerobic bacteria	≤100CFU/g	<10CFU/g
Total fungus	≤10CFU/g	<10CFU/g
Salmonella typhi	Should be absent	none detected
Staphylococcus aureus	Should be absent	none detected
Escherichia coli	Should be absent	none detected
Pseudomonas aeruginosa	Should be absent	none detected
Bacterial Endotoxins	≤0.58IU/mg	<0.58IU/mg
Assay by HPLC	Not less than 758ug of Clindamycin per mg on the anhydrous substance	846ug/mg
Conclusion	This Product Conforms with CURRENT USP	

Reviewed by: *Jinian qin*
2021.5.31

Approved by: *Ranxiaohui*
2021.5.31