

Product Name
Clindamycin phosphate USP31

(ITEMS)	(STANDARDS)	(RESULT)
Appearance	A white crystalline powder	A white crystalline powder
Solubility	Freely soluble in water, slightly soluble in Alcohol, practically insoluble in dichloromethane	Complies
Identification	A: IR spectrum D: Reaction phosphate	Complies
Crystalline	Meets the requirement	Complies
pH	3.5 – 4.5	3.7
Specific optical rotation	+115 -+130°	+123.4°
Sterility	Meets the requirement	Complies
Appearance of solution:	Clear and colorless	Complies
Water	≤ 6.0%	0.9%
Potency	≥ 758μ g/mg	827μ g/mg
Bacterial endotoxins	≤ 0.58EU/mg	Complies
Total impurities	≤ 4.0%	2.54%
Max impurity	≤ 2.5%	1.37%
Assay:	95.0% -100.5%	98.20%

CONCLUSION: COMPLY WITH THE REQUIREMENT OF USP 31 STANDARD