



AUROCHEM LABORATORIES (INDIA) PVT. LTD.

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C4-1

WORKING STANDARD REPORT

Preparation Date	20/07/2014	Valid Upto	20/07/2015
Manufacturer	Zhejiang Hisoar Pharmaceuticals Co.Ltd.	Page No.	1/1
Item Name	CLINDAMYCIN PHOSPHATE USP	Mfg. Date	DEC 2013
Batch No	P-006-WS20131203	Exp. Date	DEC 2017
Storage condition	Store below 25°C	Quantity	500 mg
TEST		OBSERVATIONS	STANDARD
01.	Description	White, hygroscopic, crystalline powder. Is practically odorless, and has a bitter taste.	White to off-white, hygroscopic, crystalline powder. Is odorless or practically odorless, and has a bitter taste.
02.	Solubility	Freely soluble in water; slightly soluble in dehydrated alcohol; very slightly soluble in acetone; practically insoluble in chloroform, in benzene, and in ether.	Freely soluble in water; slightly soluble in dehydrated alcohol; very slightly soluble in acetone; practically insoluble in chloroform, in benzene, and in ether.
03.	Identification	The IR absorption spectra of the sample concordant with the reference spectrum of Clindamycin Phosphate W.S	The IR absorption spectra of the sample concordant with the reference spectrum of Clindamycin Phosphate W.S
04.	Crystallinity	The particles show birefringence (interference colors) and extinction positions when the microscope stage is revolved.	The particles show birefringence (interference colors) and extinction positions when the microscope stage is revolved.
05.	pH (10mg/ml Solution)	3.88	3.5 to 4.5
06.	Water	0.90%	NMT 6.0%
07.	Assay C₁₈ H₃₄ ClN₂ O₈ PS	937.03 mcg/mg on anhydrous basis 928.60 mcg/mg on as is basis	NLT 785 mcg/mg on anhydrous basis

In the opinion of undersigned the sample referred to above IS OF STANDARD QUALITY as defined in the Act and Rules made thereunder in above respect, as per **USP** & can be used as **Working Standard**.

AUROCHEM LABORATORIES (I) PVT. LTD.

ANALYSED BY	CHECKED BY

Tugel Chhet
Quality Control Manager

NATIONAL QUALITY
REC-
09 OCT 2014



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