

## AUROCHEM LABORATORIES (INDIA) PVT. LTD.

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Corporate ID : U24230MH1997PTC112098

WORKING STANDARD REPORT

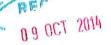
WORKING STANDARD INDICATE AND ACCOUNT OF THE PROPERTY OF THE P					
Preparation Date		20/07/2014		Valid Upto	20/07/2015
Manufacturer		Zhejiang Hisoar Pharmaceuticals Co.Ltd.		Page No.	1/1
Item Name		CLINDAMYCIN PHOSPHATE USP		Mfg. Date	DEC 2013
Batch No		P-006-WS20131203		Exp. Date	DEC 2017
Storage condition St		Store below 25°C		Quantity	500 mg
TEST		ST	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 achoroform, in benzene, and in ether.  The IR absorption spectra of the sample concordant with the reference spectrum of Clindamycin Phosphate W.S.  The particles show birefringence (interference colors) and extinction positions when the microscope stage is revolved.  3.5 to 4.5  NMT 6.0%  NLT 785 mcg/mg on anhydrous basis	
03.	Identification		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.		
05. 06 07	pH (10mg/ml Solution ) Water Assay C <sub>18</sub> H <sub>34</sub> ClN <sub>2</sub> O <sub>8</sub> PS		3.88 0.90% 937.03 mcg/mg on anhydrous basis 928.60 mcg/mg on as is 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.

ANALYSED BY CHECKED BY

AUROCHEM LABORATORIES (I) PVT. LTD.

Trupil Chur! Quality Control Manager









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