

WRS
F17P1**CORAL LABORATORIES LIMITED**

Plot No 27-28, Pharmacy, Selaqui, Dehradun 248197 (Uttarakhand)

Department: Quality Control	SOP No.	SOP/QC/001
Subject: Procedure for Preparation, Usage and Storage of Working Reference Standard	Revision No.	R-05
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CERTIFICATE OF ANALYSIS FOR WORKING STANDARD

Name of the Working Standard: Flucloxacillin Sodium BP				Working Standard No: 4	
Manufactures/Suppliers: Aurovindo Pharma Ltd/ Aurovindo Pharma Ltd				AR No. of WS: RM/B/171/14-15	
Batch No.:	1511502449	Mfg. Date	02/2015	Exp. Date	01/2018
Date of Preparation	10/07/2015	Valid upto	09/07/2016	Qty. of Working Standard	7 X 5 g
Storage Condition: Store in cool and dry place.					
Reference Standard/ material used for standardization:				Batch No:	

Sr. No.	Test	Specification / Limit	Result	
1.	Description	White or almost white, hygroscopic, crystalline	Complies	
2.	Solubility	Freely soluble in water and in methanol , soluble in ethanol (96 per cent)	Complies	
3.	Identification	The infra-red absorption spectrum	Complies	
4.	Related substances	By Liquid chromatography	Complies	
5.	Water	3.0 to 4.5% determined	Set I	3.33%
			Set II	3.15%
			Average	3.24%
6.	Assay	Not less than 98.0% and Not more than 102.0% on anhydrous basis.	Set I	94.32%
			Set II	94.39%
			Set III	94.41%
			Average	94.37%
			(As it is)	

% RSD of Assay: 0.47 % (Limit: Not more than 1.0%)

Remark: This material shall be substituted as working standard in place of the reference standard as per above performed tests.

No of Vials prepared	:	07	Date of Preparation	:	10/07/2015
Effective from	:	10/07/2015	Valid Up to	:	09/07/2016
Use within 02 months after opening					

Analysed By:	Asi/b	Checked by:	09	Approved by:	JA
Date:	10/07/2015	Date:	10/07/2015	Date:	10/07/2015

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