

**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

Page No.

1 of 1

CERTIFICATE OF ANALYSIS FOR WORKING STANDARD

Name of the Working Standard: Amoxicillin Trihydrate BP				Working Standard No: 54	
Manufactures/Suppliers: Aurobindo Pharma LTD/ Aurobindo Pharma LTD				AR No. of WS: RMB/78/13-14	
Batch No.:	KAX02140353	Mfg. Date	02/2014	Exp. Date	01/2017
Date of Preparation	19/08/2014	Valid upto	18/08/2015	Qty. of Working Standard	7 X 5 g
Storage Condition: Store in a cool and dry place, protected from light.					
Reference Standard/ material used for standardization:					Batch No: ----

Sr. No.	Test	Specification / Limit	Result	
1.	Description	White or almost white, crystalline powder.	Complies	
2.	Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides	Complies	
3.	Identification	The infra-red absorption spectrum	Complies	
4.	Related substances	By liquid chromatography.	Complies	
5.	Water	11.5 per cent to 14.5 per cent	Set I	13.80%
			Set II	13.70%
			Average	13.75%
6.	Assay	less than 95.0 % and Not more than 102.0% on anhydrous substance.	Set I	84.24%
			Set II	84.37%
			Set III	84.60%
			Average	84.40%
				(As it is)

% RSD of Assay: 0.215% (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	:	19/08/2014
Effective from	:	19/08/2014	Valid Up to	:	18/08/2015
Use within 02 months after opening					



Analysed By:		Checked by:		Approved by:	
Date:	19/08/2014	Date:	19/08/2014	Date:	19/08/2014