

Sun Pharmaceutical Ind. Ltd.
Certificate of Analysis

Working Standard

Material	: BETAHISTINE DIHYDROCHLORIDE BP (WORKING STANDARD)		
WS No	: WS14053	AR No	: IP058/05/14
Spec Code	: WSBD0048B0	Rev No	: 1.0
Evaluated Against	: EPCRS	Lot/Batch/Code No. Valid Up to Date	: 2.0
Mfg Date	: Oct/2013	Exp. Date	: Sep/2016
Reference	: As per BP		
Effective Date	: 29/05/2014	Use Before Date	: 29/05/2016
Quantity Prepared	: 190000 mg	No. of Containers Prepared	: 52
Intended Use	: For qualitative & quantitative analysis	Direction for Use	: As Such (single time use)

Sr.	Test	Observation/Results	Specification	Analyst-Method-Test
	Impurity B	BQL (<0.03)		
	Impurity C	BQL (<0.03)		
	UnKnown Impurities			
	Unspecified impurity	BQL (<0.03)		
	Total impurities	BQL		
5	Assay by titrimetry			HCM - T0008
5.1	Assay - By Titrimetry (Set - I)	On dried basis 99.9% On as is basis 99.2%	Not less than 99.0% and not more than 101.0% of Betahistine dihydrochloride, calculated on dried basis.	HCM - M2268 6-T126
5.2	Assay - By Titrimetry (Set - II)	On dried basis 100.3% On as is basis 99.6%	Not less than 99.0% and not more than 101.0% of Betahistine dihydrochloride, calculated on dried basis.	HCM - M2268 6-T1267
5.3	Mean Assay	On dried basis 100.1% On as is basis 99.4%	Not less than 99.0% and not more than 101.0% of Betahistine dihydrochloride, calculated on dried basis.	HCM - M1436 4-T3573

BQL = Below Quantification Limit

Remarks : The substance complies against the standard and qualifies for usage as a working standard.
Storage : Store in a well - closed container at temperature below 25°C , Very hygroscopic.