

**Sun Pharmaceutical Ind. Ltd.**  
**Certificate of Analysis**

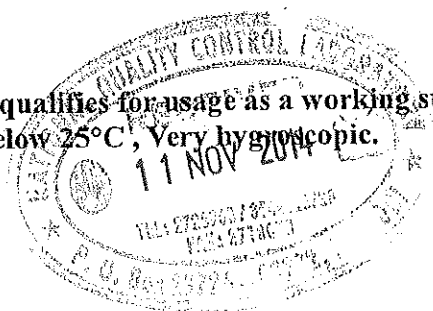
**Working Standard**

<b>Material</b>	: BETAHISTINE DIHYDROCHLORIDE BP (WORKING STANDARD)		
<b>WS No</b>	: WS14053	<b>AR No</b>	: IP058/05/14
<b>Spec Code</b>	: WSBD0048B0	<b>Rev No</b>	: 1.0
<b>Evaluated Against</b>	: EPCRS	<b>Lot/Batch/Code No. Valid Up to Date</b>	: 2.0
<b>Mfg Date</b>	: Oct/2013	<b>Exp. Date</b>	: Sep/2016
<b>Reference</b>	: As per BP		
<b>Effective Date</b>	: 29/05/2014	<b>Use Before Date</b>	: 29/05/2016
<b>Quantity Prepared</b>	: 190000 mg	<b>No. of Containers Prepared</b>	: 52
<b>Intended Use</b>	: For qualitative & quantitative analysis	<b>Direction for Use</b>	: 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-T1267
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.



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<b>Checked By</b>	<b>Approved By</b>
VIPUL B PRAJAPATI - E21906 29/05/2014	SANDEEP RAJURKAR - E30201 29/05/2014

**Generated By**      **HIREN C MEHTA**  
**Date**                      **29/05/2014**