

Sun Pharmaceutical Ind. Ltd. Certificate of Analysis			
Working Standard			
Material	:	BETAHISTINE DIHYDROCHLORIDE BP (WORKING STANDARD)	
WS No	:	WS16026	AR No : IP050/02/16
Spec Code	:	WSBD0048B0	Rev No : 1.0
Evaluated Against	:	EPCRS	Lot/Batch/Code No. Valid Up to Date : 2.0
Mfg Date	:	Dec/2014	Exp. Date : Nov/2017
Reference	:	As per BP	
Effective Date	:	08/03/2016	Use Before Date : 23/11/2017
Quantity Prepared	:	95000 mg	No. of Containers Prepared : 48
Intended Use	:	For qualitative & quantitative analysis	Direction for Use : As Such ( single time use )

Sr.	Test	Observation/Results	Specification
1	Description	White crystalline powder, very hygroscopic.	White to slightly yellow powder, very hygroscopic.
2	Identification - by IR	The Infrared spectrum of the sample is concordant with that the spectrum of the Betahistine Dihydrochloride EPCRS.	The Infrared spectrum of the sample should be concordant with that the spectrum of the Betahistine Dihydrochloride Reference Standard.
3	Loss on drying - Sample Weight 1.0 gm at 105° upto Constant Weight	Mean : 0.27 %	Maximum 1.0%, determined on 1.000 by drying in an oven at 105°C
4	Related substances by HPLC		
4.1	Related Substances - Method I		
	Known Impurities		
	impurity A	BQL (<0.03)	impurity A : Not more than 0.2 %
	impurity B	BQL (<0.03)	impurity B : Not more than 0.2 %
	impurity C	BQL (<0.03)	impurity C : Not more than 0.2 %
	UnKnown Impurities		Unspecified impurity : Not more than 0.1 %
	Unspecify impurity	BQL (<0.03)	
4.2	Related Substances - Method II		
	Known Impurities		Total impurities : Not more than 0.5 %
	Impurity A	BQL (<0.03)	

Address: Survey No.214, Plot No.20, Govt.Ind.Area Phase II, Piparia, Silvassa, 396230 (U.T. of D&NH)  
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Sr.	Test	Observation/Results	Specification
	Impurity B	BQL (<0.03 )	
	Impurity C	BQL (<0.03)	
	UnKnown Impurities		
	Unspecified impurity	BQL (<0.03)	
	Total impurities	BQL	
5	Assay by titrimetry		
5.1	Assay - By Titrimetry (Set - I)	On dried basis 100.2% On as is basis 99.9%	Not less than 99.0% and not more than 101.0% of Betahistine dihydrochloride, calculated on dried basis.
5.2	Assay - By Titrimetry (Set - II)	On dried basis 99.4% On as is basis 99.1%	Not less than 99.0% and not more than 101.0% of Betahistine dihydrochloride, calculated on dried basis.
5.3	Mean Assay	On dried basis 99.8% On as is basis 99.5%	Not less than 99.0% and not more than 101.0% of Betahistine dihydrochloride, calculated on dried basis.

BQL = Below Quantification Limit



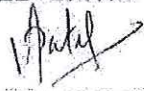
Remarks : The substance complies against the standard and qualifies for usage as a working standard.

Storage : Store in a well - closed container at temperature below 25°C , Very hygroscopic.

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Data Entered By	Checked By	Approved By
MINALKUMAR R PATEL - E38523 06/03/2016 	VIPUL B PRAJAPATI - E21906 06/03/2016 	ASHWIN D PATEL - E36632 08/03/2016 

Generated By **HIREN C MEHTA, E17588**  
Date **08/03/2016**



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