

Pure & Cure Healthcare Pvt. Ltd.

Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur
Haridwar-249403, Uttarakhand, INDIA.

QUALITY CONTROL**CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	VERTIHIST-16		
Generic Name :	Betahistine Tablets IP		
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC
Batch No. :	PA2BE08	A. R. No.:	F20240406008
Mfg. Date :	Apr. 2024	Pack Size:	1x15 Tabs
Expiry date:	Mar. 2026	Pack Type:	Alu-Alu Blister (Sale)
Batch Size :	300000 Tabs	Sampled On:	06/04/24
Product Code :	40050069	Sample Quantity:	135 Tabs
Specification No, Ver No.:	STS/FP/40050069-02	Sampled By:	AJIT KUMAR RAO
Ref. STP No. , Ver No.:	STP/FP/0038-02	Analyzed By:	HARKISHAN
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	06/04/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	Analysis Completion Date:	09/04/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White to off white coloured, round, biconvex, both side plain uncoated tablets. 15 tablets packed in an alu-alu blister of printed aluminium foil and printed base aluminium foil.	White coloured, round, biconvex, both side plain uncoated tablets. 15 tablets packed in an alu-alu blister of printed aluminium foil and printed base aluminium foil.

	Prepared By QC	Reviewed By QC	Approved By QC
Date	09/04/24	09/04/24	09/04/24
Name	ROBIN KUMAR	SHRAVAN	RAJESHWAR SINGH
Designation	ASST. OPERATOR	ASST. MANAGER	DY. MANAGER

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Name : RAVINDRA GOSAVI ; Date : 09/04/2024

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2	Identification	(A) By IR: The IR spectrum of the test preparation should concordant to that of the reference preparation of Betahistine Hydrochloride reference standard or working standard. (B) By HPLC: In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution of Betahistine Hydrochloride.	Complies
3	Dimension	As below	As below

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
a.	Diameter	8.0 mm $\pm$ 0.2 mm (7.8 mm to 8.2 mm)	Min. 8.03 mm Max. 8.05 mm
b.	Thickness	3.6 mm $\pm$ 0.3 mm (3.3 mm to 3.9 mm)	Min. 3.40 mm Max. 3.44 mm
4	Average weight	171.0 mg $\pm$ 7.5%	169.22 mg
5	Uniformity of weight	Not more than two of individual weight deviate from the average weight by more than 7.5% and none deviates by more than 15%.	-7.2% to +4.8%
6	Disintegration Time	Not more than 15 minutes	Passes (01 Minutes 40 Seconds)
7	Hardness	Not less than 30 Newton	Min. 32 Newton Max. 43 Newton
8	Friability	Not more than 1.0% w/w	0.79 %w/w

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
9	Dissolution	Level S1 (No. of tablets Tested 6 units): Each unit is not less than 80 % (Q) which is equivalent to 85 % of the labelled amount is released. Level S2 (No. of tablets tested 6 units): Average of 12 units (S1 + S2) is equal to or greater than 80 % and no unit is less than 65 % (Q – 15 %). Level S3 (No. of tablets tested 12 units): Average of 24 units (S1 + S2 + S3) is equal to or greater than 80 % not more than 2 units are less than 65 % (Q – 15 %) and No unit is less than	91.26%, 94.26%, 85.93%, 89.60%, 94.26%, 94.26%

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		55 % (Q – 25 %).	

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
10	Uniformity of content	The preparation complies with the test if each individual content is 85 to 115 per cent of the average content. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside the limits of 75 to 125 per cent of the average content. If one individual content is outside the limits of 85 to 115 per cent of the average content but within the limits of 75 to 125 per cent, repeat the determination using another 20	92.36% to 108.66%

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		dosage units. The preparation complies with the test if not more than one of the individual contents of the total sample of 30 dosage units is outside 85 to 115 per cent of the average content and none is outside the limits of 75 to 125 per cent of the average content.	
11	Related Substance	As below	As below
a.	Betahistine Impurity C	Not more than 2.0%	Below disregard limit.
b.	Betahistine Impurity A	Not more than 0.2%	Below disregard limit.
c.	Any other secondary impurity	Not more than 0.2%	Below disregard limit.

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d.	Sum of all the secondary impurities	Not more than 2.0%		Below disregard limit.
12	Assay - Each uncoated tablet contains:	Shelf Life Limit	Release Limit	
	Betahistine Hydrochloride IP - 16 mg/Tab	NLT 15.20mg/Tab to NMT 16.80mg/Tab (NLT 95.00% to NMT 105.00% of label claimed)	NLT 15.52mg/Tab to NMT 16.80mg/Tab (NLT 97.00% to NMT 105.00% of label claimed)	16.19mg 101.19%

CONCLUSION : The Finished Product complies as per IP Specifications.

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