

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-24		
Generic Name :	Betahistine Hydrochloride Sustained Release Tablets 24 mg		
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC
Batch No. :	PA2BF06	A. R. No.:	F20240427048
Mfg. Date :	Apr. 2024	Pack Size:	1x15 Tabs
Expiry date:	Mar. 2026	Pack Type:	Alu-Alu Blister (Sale)
Batch Size :	150000 Tabs	Sampled On:	27/04/24
Product Code :	40051762	Sample Quantity:	90 Tabs
Specification No, Ver No.:	STS/FP/40051762-00	Sampled By:	SHIVAM
Ref. STP No. , Ver No.:	STP/FP/0389	Analyzed By:	ANJALI PUNDIR
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	27/04/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	Analysis Completion Date:	04/05/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White to off white coloured, round, biconvex, plain on both side & film coated sustained release tablets. 15 tablets packed in an alu-alu blister of printed aluminium foil & base aluminium foil.	White coloured, round, biconvex, plain on both side & film coated sustained release tablets. 15 tablets packed in an alu-alu blister of printed aluminium foil & base aluminium foil.
2	Identification	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.	Complies
3	Dimension	As below	As below
a.	Diameter	9.8 mm $\pm$ 0.2 mm	Min. 9.76 mm Max. 9.78 mm

	Prepared By QC	Reviewed By QC	Approved By QC
Date	04/05/24	04/05/24	04/05/24
Name	UDAY	PRAMOD KUMAR	YOGESH CHAUHAN
Designation	OPERATOR	DY. MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : SHEKHAR PUNDIR ; Date : 06/05/2024

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b.	Thickness	4.2 mm $\pm$ 0.4 mm	Min. 4.12 mm Max. 4.34 mm
4	Average weight	315.0 mg $\pm$ 5.0%	315.13 mg
5	Uniformity of weight	Not more than two of individual weight deviate from the average weight by more than 5% and none deviates by more than 10%.	-1.5% to +1.2%
6	Dissolution	As below	As below
a.	After 1 hour	15 % to 45 %	35.58%, 38.22%, 37.66%, 38.75%, 36.23%, 35.05%
b.	After 4 hours	50 % to 85 %	70.88%, 73.67%, 72.97%, 69.62%, 70.77%, 71.84%
c.	After 12 hours	Not less than 80%	98.36%, 93.91%, 98.73%, 98.65%, 93.25%, 98.59%

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
7	Uniformity of content	85% to 115% of average value		98.01% to 103.42%
8	Assay - Each film coated sustained release tablet contains:	Shelf Life Limit	Release Limit	
a	Betahistine Hydrochloride IP - 24 mg/Tab	NLT 21.60mg/Tab to NMT 26.40mg/Tab (NLT 90.00% to NMT 110.00% of label claimed)	NLT 22.80mg/Tab to NMT 26.40mg/Tab (NLT 95.00% to NMT 110.00% of label claimed)	23.80mg 99.17%

CONCLUSION : The Finished Product complies as per IH Specifications.

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