



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	BETAHISTINE DIHYDROCHLORIDE Ph.Eur./BP	CAS No:	5579-84-0
Batch No.	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White or slightly yellow powder, very hygroscopic	Slightly yellow powder, very hygroscopic
2	Solubility	Very soluble in water, soluble in ethanol (96 per cent), practically insoluble in 2-propanol	Complies
3	Identification by -Melting point	Between 150°C to 154°C	Complies
4	Identification by -IR	The IR spectrum of test sample is concordant with that spectrum obtained with working standard.	Complies
5	Identification by - TLC	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.	Complies
6	Identification by -Reaction (a) of chlorides	Should be gives reaction (a) of chlorides	Complies
7	Appearance of solution (10% w/v in water)	Solution S should be clear and note more intensely colored than Reference solution $\text{B}_{8\%}$	Complies
8	pH (10% w/v in water)	Between 2.0 and 3.0	2.46
9	Related substance by HPLC Impurity-A	Not more than 0.2%	Not detected
10	Related substance by HPLC Impurity-B	Not more than 0.2%	Not detected
11	Related substance by HPLC Impurity- C	Not more than 0.2%	Not detected
12	Related substance by HPLC Any other impurity	Not more than 0.10%	0.01%
13	Related substance by HPLC Total impurities	Not more than 0.5%	0.01%
14	Loss on drying (at 105°C)	Not more than 1.0% w/w	0.45%
15	Sulphated ash	Not more than 0.1% w/w	0.06%
16	Assay by titration (on dried basis)	Between 99.0% and 101.0% w/w	100.4%

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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