



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	BILASTINE IP	CAS No:	202189-78-4
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	A white to creamy white powder.	A White powder
2	Solubility	Slightly soluble in methanol. Very Slightly soluble in dimethyl sulphoxide, practically insoluble in water.	Complies
3	Identification by -IR	IR spectrum of test sample should be concordant with that of the standard	Complies
4	Identification by -HPLC	In the assay, the principal peak in the Chromatogram obtained with the test Solution corresponds to the principal Peak in the chromatogram obtained with the reference solution.	Complies
5	Loss on drying	Not More than 1.0 per cent	0.350%
6	Heavy metal	Not more than 20 ppm	Complies
7	Sulphated ash	Not More than 0.1 per cent	0.018%
8	Related Substance by HPLC Impurity A	Not more than 0.5%	Complies
9	Related Substance by HPLC Impurity B	Not more than 0.5%	Complies
10	Related Substance by HPLC Impurity C	Not more than 0.5%	Complies
11	Related Substance by HPLC Impurity D	Not more than 0.5%	Complies
12	Related Substance by HPLC Impurity E	Not more than 0.5%	Complies
13	Related Substance by HPLC Any individual unspecified impurity	Not more than 0.3%	Complies
14	Related Substance by HPLC Total impurity	Not more than 1.0%	Complies
15	Assay	Not less than 98.0 per cent and not More than 102.0 per cent on the Dried basis.	99.897%

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By	Checked by	Approved By
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Sonali Nirmal
Date: 23/05/2026



Dadarao Kakde
Date: 23/05/2026



Nayna Nehete
Date: 23/05/2026



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