



INNOVA CAPTAB LTD
1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I,
JHARMAJRI, BADDI (HP) INDIA

Certificate of Analysis

Product Name: Bilastiheal-20

Generic Name	Bilastine Tablets IP	Packing Code	GD710017
Batch Log No	32452182	Packing Batch No	GD714010B
Bulk Batch No	GD714010	Batch Size	5.0 Lac
Packing Type	(10*1*10) Tablets	Date of Analysis	23/11/2024
A.R. No.	2003FP324006044	Reference	IP
Mfg. Date	11/2024	Exp. Date	10/2026
Specification No	FPS-GD71-04	Date of Release	14/12/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	White colored, round shaped, biconvex film coated tablets plain on both sides	White colored, round shaped, biconvex film coated tablets plain on both sides
2	Identification (By High Performance Liquid Chromatography)	In the Assay, the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with standard solution	In the Assay, the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with standard solution
3	Average weight	83.0mg $\pm$ 7.5%	84.57 mg
4	Uniformity of weight	$\pm$ 7.5% of avg. wt.	%Maximum +ve deviation : 2.6 % %Maximum -ve deviation:-4.3 %
5	Disintegration time	Not more than 30 minutes	Disintegration time:0.57 Minutes
6	Dissolution Apparatus-Basket, 100rpm, 500ml of 0.1M Hydrochloric acid, 15 minutes)	Not less than 80% (Q) of the stated amount of Bilastine should be dissolved in 15 minutes.	Min : 99.4 % Max : 99.7 % Average:99.5 %
7	Uniformity of dosage units		
7.1	For Bilastine by using content uniformity method (By HPLC)	Acceptance Value $\leq$ 15.0	Acceptance value:0.99 NA
8	Assay-Each Film Coated tablet contains:		
8.1	Bilastine IP.....20mg	18.00 mg to 22.00mg [90.0% to 110.0% of Labeled claim)	Assay % of Label Claim: : 100.7 % Assay:mg/Tab:20.13 mg/tab
9	Related Substance		
9.1	Bilastine Impurity B	Not more than 1.0%	BDL
9.2	Bilastine Impurity F	Not more than 1.0%	BDL
9.3	Any other secondary impurity	Not more than 0.5%	0.14%
9.4	Total impurities	Not more than 2.0%	0.16%
10	Additional Tests		
10.1	Residual solvent by GC		
10.1.1	Isopropyl alcohol	Not more than 5000ppm	Not Detected
10.1.2	Methylene chloride	Not more than 600ppm	Not Detected

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By	Reviewed By	Approved By
ranjit.nayak(Analyst)	satyendra.p(Chemist)	omprakash.sharma(Manager)
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