

		INNOVA CAPTAB LTD 1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI (HP) INDIA	
Certificate of Analysis			
Product Name: Bilastiheal M			
Generic Name	Bilastine and Montelukast Tablets	Packing Code	GD900013
Batch Log No	32453871	Packing Batch No	GD904021A
Bulk Batch No	GD904021	Batch Size	4.0 Lac
Packing Type	10*10 Tablets	Date of Analysis	01/12/2024
A.R. No.	2003FP324006207	Reference	In house
Mfg. Date	11/2024	Exp. Date	10/2026
Specification No	FPS-GD90-01	Date of Release	10/12/2024

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	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	184.0mg $\pm$ 7.5%	182.09 mg
4	Uniformity of weight	$\pm$ 7.5% of average weight	%Maximum +ve deviation : 3.1 % %Maximum -ve deviation:-3.4 %
5	Disintegration time	Not more than 30 minutes	Disintegration time:1.53 Minutes
6	Uniformity of content		
6.1	Bilastine	Between 85.0% and 115.0% of average content.	Max : 100.9 % Min:99.5 %
6.2	Montelukast Sodium	Between 85.0% and 115.0% of average content.	Max : 101.2 % Min:99.6 %
7	Dissolution		
7.1	Bilastine	Not less than 70% of labeled amount of Bilastine should be dissolved in 45 minutes	Min: : 94.0 % Max: : 97.7 % Average::95.6 %
7.2	Montelukast Sodium	Not less than 70% of labeled amount of Montelukast Sodium should be dissolved in 45 minutes	Min: : 97.5 % Max: : 97.8 % Average::97.6 %
8	Bilastine IP.....20mg	18.00mg to 22.00mg (90.00% to 110.00% of Labelled claim)	Assay % of Label Claim : 101.3 % Assay:mg/Tab:20.27 mg/tab

Remarks: APPROVED (Sample conforms to above Specification)		
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Prepared By	Reviewed By	Approved By
jagdish.singh(Analyst)	omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
10/12/2024 14:11	10/12/2024 14:21	10/12/2024 14:57
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S. No.	TEST	SPECIFICATION	RESULT
9	Assay-Each Film Coated tablet contains:		
9.1	Montelukast Sodium IP Eq. to Montelukast.....10mg	9.00mg to 11.00mg (90.0% to 110.0% of label claim)	Assay % of Label Claim: : 101.3 % Assay:mg/Tab:10.13 mg/tab
9.2	Related Substances		
9.2.1	Maximum single impurity	Not more than 1.5%	0.17 %
9.2.2	Total impurities	Not more than 2.0%	0.39 %

Remarks: APPROVED (Sample conforms to above Specification)

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