



ZEE LABORATORIES
UCHANI, G.T. ROAD KARNAL HR INDIA 132001

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. : 262710051

Document No. : 262710856

Ref. STS No.	STP00226	Product Code	FG00163
Product Name	BILAZEE-M TABLETS (10X10)		
Generic Name	BILASTINE 20 MG. & MONTELUKAST 10 MG. BILAYERED I.P. TABLETS		
Batch No.	ZIT0122	Date Of Sampling	31/05/2026
Batch Size	101000.000 TAB	Cumulative Qty.	99150
Mfg. Date	04/2026	Exp. Date	03/2029
A. R. No.	KP26FG00436	Quantity Release	99090.000 TAB
		Date Of Release	31/05/2026

S NO.	Tests	Specification	Results
1	Description	White and pink colour bilayered film coated tablet.Both sides are smooth.	White and pink colour bilayered film coated tablet.Both sides are smooth.
2	Identification	Postive for Bilastine & Montelukast sodium	Postive for Bilastine & Montelukast sodium
3	Avg. weight of tablet	224 mg. $\pm$ 7.5%	220.68 mg
4	Uniformity of tablet	$\pm$ 7.5% of the average weight	-2.12%, +2.59 %
5	Disintegration Test	NMT 30 Minutes	05:06 Minute
6	Assay(Each film-coated tablet contain);	-	--
7	Bilastine I.P. 20 mg	NLT 90.0% & NMT 110.0% of labeled amount of Bilastine	106.11 %
8	Montelukast Sodium I.P. 10 mg eq. to montelukast	NLT 90.0% & NMT 110.0% of labeled amount of Montelukast sodium	98.01 %

Remarks The above sample complies/~~does not~~ comply with prescribed standards of Quality with respect to above tests as per IP/BP/USP/In-house specification.

Prepared By

Date 31/05/2026

Checked By

Date 31/05/2026

