

Lanark Laboratories

NEAR ELECTRICITY SUB DIVISION, GONDPUR, PAONTA SAHIB DISTT.SIRMOUR HP INDIA 173025

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

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

Work Order No.: 242519685

Document No.: 242527656

Ref. STS No.	7929	Product Code	FG01622
Product Name	TAB. MIONTIZEE-L (ZLP)		
Generic Name	MONTELUKAST SODIUM WITH LEVOCETIRIZINE HCL TABLTES I.P		
Batch No.	425-185	Date Of Sampling	10/03/2025
Batch Size	700000.000 TAB	Cumulative Qty.	696220.000 TAB
Mfg. Date	03/2025	Sample Quantity	60.000 TAB
	Exp. Date 08/2027	Quantity Release	696160.000 TAB
A. R. No.	PL25FG00852	Date Of Release	18/03/2025

S NO.	Tests	Specification	Results
1	Description	A white colour round shape biconvex film coated tablet plain on both sides.	A white colour round shape biconvex film coated tablet plain on both sides.
2	Identification	Positive for Montelukast sodium & Levocetirizine HCl.	Complies
3	Average weight	122mg $\pm$ 7.5% of average weight	121.0 mg
4	Uniformity of weight	$\pm$ 7.5% of average weight	-3.61%, +1.84%
5	Disintegration Time	NMT 30 Minutes	01 Min 55 Sec
6	Uniformity of content	Limit	Result
7	Montelukast sodium I.P. eq. to Montelukast 10 mg.	85.00% to 115.00%	89.63% to 104.45%
8	Levocetirizine Hydrochloride I.P. 5 mg.	85.00% to 115.00%	92.12% to 109.87% -
9	Dissolution	Limit	Result
10	Montelukast sodium I.P. eq. to Montelukast 10 mg.	Not less than 75 %	Mean-111.56 %
11	Levocetirizine Hydrochloride I.P. 5 mg.	Not less than 75 %	Mean-96.90 %
12	Composition: Each film coated tablet contains:	Limit	Assay
13	Montelukast Sodium I.P. eq. to Montelukast 10 mg.	90.0 to 110.0% w/w of the stated amount of Montelukast Sodium.	105.46 %
14	Levocetirizine HCl I.P. 5 mg.	90.0 to 110.0% w/w of the stated amount of Levocetirizine HCl.	103.52 %

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

Checked By

Date 18/03/2025

Date 18/03/2025

QC/M

Approved By

Date 18/03/2025

Appendix No.: -

Confidential

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