

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	MONTAHEAL-LC TABLETS		
Generic Name/Dosage Form Strength (mg)	Montelukast Sodium 10 mg & Levocetirizine Hydrochloride 5 mg Tablets IP		
Batch No.	MHT23001	A.R. No.	QC/FG/23/08684
Batch Size	750000 TABLET	Pack Size	10 X 15 TABLET
Mfg. Date	09/2023	Exp. Date	08/2026
Reference	I.P	Market	Domestic
Sample Received on	12/10/2023	Sample Qty.	1x90 TABLET
Ref. STP No.	WBL/STP/FG/0032	Ref. SPS No.	WBL/FPS/FG/5388
Date of Analysis started on	13/10/2023	Date of Analysis completed on	19/10/2023
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S.No.	Test	Specification	Result
1	Description	White and light pink coloured, round, bilayered, flat faced, beveled edge uncoated tablets scored on one side & plain on other side.	White and light pink coloured, round, bilayered, flat faced, beveled edge uncoated tablets scored on one side & plain on other side.
2	Identification	In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the principal peaks in the chromatogram obtained with reference solution (c).	Complies
3	Diameter	6.95 mm to 7.35 mm	Min = 7.11 mm Max = 7.17 mm
4	Thickness	2.70 mm to 3.10 mm	Min = 2.7 mm Max = 2.76 mm
5	Hardness	Not less than 3.0 Kgf	5.22 Kgf
6	Friability	Not more than 1.0% w/w	0.22 % w/w
7	Disintegration Time	Not more than 15 minutes	04 Min 12 Sec
8	Average weight	135.80 to 144.20 mg	140.54 mg
9	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 7.5%. No tablet deviates from the average weight by more than 15%.	deviation -2.71 to +2.81%
10	Dissolution		
10a.	70% (Q) Montelukast Sodium IP eq. to Montelukast	Not less than 75.0% of the stated amount in 45 minutes	Min-93.7% Max-98.8% Avg-96.8%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	ROHIT RAWAT	Ravi Kumar	Nidhi Rani	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Sr. Officer	G. M.
Date	19/10/2023	20/10/2023	20/10/2023	20/10/2023

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S.No.	Test	Specification	Result
10b.	70% (Q) Levocetirizine Dihydrochloride IP	Not less than 75.0% of the stated amount in 45 minutes	Min-96.6% Max-101.8% Avg-99.8%
11	Uniformity of dosage units (By Content uniformity)		
11a.	Montelukast Sodium IP eq. to Montelukast	Acceptance value should be less than 15	6.00
11b.	Levocetirizine Dihydrochloride IP	Acceptance value should be less than 15	6.40
12	Related substances		
12a.	Montelukast Sulphoxide impurity	Not more than 2.0%	0.241%
12b.	Montelukast Styrene impurity	Not more than 1.0%	0.232%
12c.	Any other secondary impurity	Not more than 1.0%	0.068%
12d.	Sum of all impurities	Not more than 4.0%	0.621%
13	Assay Each uncoated bilayered tablet contains:		
13a.	Montelukast Sodium IP eq. to Montelukast...10mg	90.0 to 110.0%	104.9%
13b.	Levocetirizine Dihydrochloride IP...5mg	90.0 to 110.0%	98.8%

Remarks : In the opinion of undersigned the sample refer to above specifications complies with I.P

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
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