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.	MHT24005	**A.R. No.**	QC/FG/24/09305
Batch Size	100000 STRIP	**Pack Size**	1 X 15 TABLET
Mfg. Date	08/2024	**Exp. Date**	07/2027
Reference	I.P	**Market**	Domestic
Sample Received on	08/09/2024	**Sample Qty.**	1x150 TABLET
Ref. STP No.	WBL/STP/FG/0032	**Ref. SPS No.**	WBL/FPS/FG/5388
Date of Analysis started on	10/09/2024	**Date of Analysis completed on**	30/09/2024
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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	Friability	Not more than 1.0% w/w	0.33 % w/w
4	Disintegration Time	Not more than 15 minutes	04 Min 52 Sec
5	Average weight	135.80 to 144.20 mg	139.38 mg
6	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%.	-1.71% to +0.93%
7	Dissolution		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Vandana Benwal	Kamlesh Upreti	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager-QC	Assistant Manager-QA	G. M.
Date	30/09/2024	30/09/2024	30/09/2024	30/09/2024

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S.No.	Test	Specification	Result
7a.	Montelukast Sodium IP eq. to Montelukast	Not less than 70% (Q) of the stated amount in 45 minutes Stage: S1 Number tested: 6 Each unit is not less than Q+5 percent of the labelled content. Stage: S2 Number tested: 6 Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15 percent of the labelled content. Stage: S3 Number tested: 12 Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15 percent of the labelled content and no unit is less than Q-25 percent of the labelled content.	Min-98.2% Max-104.9% Avg-101.1%

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Date	30/09/2024	30/09/2024	30/09/2024	30/09/2024

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Batch Size	100000 STRIP	**Pack Size**	1 X 15 TABLET
Mfg. Date	08/2024	**Exp. Date**	07/2027
Reference	I.P	**Market**	Domestic
Sample Received on	08/09/2024	**Sample Qty.**	1x150 TABLET
Ref. STP No.	WBL/STP/FG/0032	**Ref. SPS No.**	WBL/FPS/FG/5388
Date of Analysis started on	10/09/2024	**Date of Analysis completed on**	30/09/2024
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S.No.	Test	Specification	Result
7b.	Levocetirizine Dihydrochloride IP	Not less than 70% (Q) of the stated amount in 45 minutes Stage: S1 Number tested: 6 Each unit is not less than Q+5 percent of the labelled content. Stage: S2 Number tested: 6 Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15 percent of the labelled content. Stage: S3 Number tested: 12 Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15 percent of the labelled content and no unit is less than Q-25 percent of the labelled content.	Min-96.4% Max-103.9% Avg-101.2%
8	Uniformity of dosage units (By Content uniformity)		
8a.	Montelukast Sodium IP eq. to Montelukast	Acceptance value should be less than 15	5.11
8b.	Levocetirizine Dihydrochloride IP	Acceptance value should be less than 15	5.37
9	Related substances		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
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Date	30/09/2024	30/09/2024	30/09/2024	30/09/2024

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Ref. STP No.	WBL/STP/FG/0032	**Ref. SPS No.**	WBL/FPS/FG/5388
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S.No.	Test	Specification	Result
9a.	Montelukast Sulphoxide impurity	Not more than 2.0%	0.14%
9b.	Montelukast Styrene impurity	Not more than 1.0%	0.17%
9c.	Any other secondary impurity	Not more than 1.0%	0.55%
9d.	Sum of all impurities	Not more than 4.0%	1.44%
10	Assay Each uncoated bilayered tablet contains:		
10a.	Montelukast Sodium IP eq. to Montelukast...10mg	90.0 to 110.0%	98.5%
10b.	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

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Date	30/09/2024	30/09/2024	30/09/2024	30/09/2024