



HANUCHEM LABORATORIES

Parwanoo (H.P)

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CERTIFICATE OF ANALYSIS

Product Name:	Montelvo (Montelukast Sodium & Levocetirizine Hcl Tablets IP)		
Batch No.	HCL4256	A. R. No.	FG/24316
Mfg. Date	May-2024	Exp. Date	Apr-2026
Batch Size	3.0 Lacs	Analysis Date	11/06/2024
Sample Quantity	60 Tablets	STP No.	FPS076

Sr. No	Tests	Results	Specification Limit
1	Description	Light yellowish colored, round shaped, biconvex film coated tablets plain on both side.	White to light yellowish colored, round shaped, biconvex film coated tablets plain on both side.
2	Identification (A) Montelukast sodium (B) Levocetirizine HCL	Complies Complies	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3	Average weight	0.1842 gm ✓	NLT- 0.17205 g to NMT- 0.2000 g (0.186 g $\pm$ 7.5 %)
4	Uniformity of weight	Min : - 3.31% Max: + 1.74% ✓	Not more than two of the individual weights deviate from the average weight by more than $\pm$ 7.5% and none deviates by more than $\pm$ 15.0%
5	Thickness	Min: 3.51 mm Max: 3.70 mm	3.5 $\pm$ 0.3mm (Limit: 3.2 to 3.80 mm)
6	Hardness	Min: 4.0 kg/cm2 Max: 4.5 kg/cm2 ✓	NLT 3.0 kg/cm2

	Prepared By	Checked By	Approved By
Name	Vikas Yadav	Rajan Mishra	Sameer Kumar
Designation	QC officer	officer	Quality control Head
Sign/Date	 11/06/24	 11/06/24	 11/06/24



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7	Dissolution A) Montelukast Sodium B) Levocetirizine Hcl	Min: 78.09% Max: 90.54% Avg: 82.99% Min: 88.46% Max: 93.66% Avg: 90.97%	NLT 70.0 % (D) of labeled amount of Montelukast Sodium & Levocetirizine Hcl at 45 Minutes.
8	Related Substance Any Secondary Peak Sum of all Secondary Peak	0.21% 0.270%	NMT 2.0 % NMT 4.0 %
9	Uniformity of Content A) Montelukast Sodium B) Levocetirizine Hcl	Min : 91.82% Max: 97.25% Avg: 93.99% Min : 96.50% Max: 100.30% Avg: 97.94%	85.0% to 115.0% of the Labeled contains of Montelukast sodium & Levocetirizine Hcl
10	Assay: Each film coated tablet contains	9.906mg 99.06% 5.11 mg 102.10%	Montelukast sodium IP Eq to Montelukast.....10 mg (Limit-NLT-9.0 mg to NMT-11 mg) (NLT-90.0% to 110.0% of labeled claim) Levocetirizine Hcl IP.....5.0 mg (Limit-NLT-4.5 mg to NMT-5.5mg) (NLT-90.0% to 110.0% of Labeled claim)

Remarks: The above sample Complies/Does not comply as per IP/BP/USP/Inhouse Specification

	Prepared By	Checked By	Approved By
Name	Nikas Yadav	Rajan Mishra	Sanjeev Kumar
Designation	QC officer	officer	Quality Control Head
Sign/Date	Nikas 11/06/24	11/06/24	11/06/24