astonea Labs Limited

ASTONEA LABS LIMITED

VILLAGE HARIPUR TEHSIL RAIPUR RANI
-134204 Haryana,India

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

The Drugs & Cosmetics Act 1940 at the under form 39

Document No. : 60658

Ref. STS No.	STS/ FG011890	**Product Code**	FG011890
Product Name	MONTELVO Tablet 10*10 AluAlu TITANIUM DIOXIDE IP 6.5 MM A3		
Generic Name	MONTELUKAST SODIUM 10MG + LEVOCETIRIZINE HYDROCHLORIDE 5MG FILM COATED (SIZE 6.5 MM C		
Batch No.	26081142P	**Date Of Sampling**	09/10/2026
Batch Size	195100 PCS	**Sample Quantity**	100.00 NOS
Mfg. Date	09/2026	**Exp. Date**	08/2028
A.R. No.	AL26FG009219	**Date Of Release**	14/10/2026

S.No.	Tests	Specification	Results
1	Description	A white colored round shape, biconvex, film coated tablet, plain on both side	Complies
2	Identification	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	Avg. weight of Tablet	115.0 mg ± 10.0 %	114.6 mg
4	Uniformity of Weight	± 10.0 % of Average weight	-2.37 % to +3.02 %
5	Disintegration test	Not more than 30 minutes.	2 minute
6	Dissolution Test	NLT- 70 % (Q) of the stated amounts of Montelukast	97.61 %
7	Dissolution Test	NLT- 70 %(Q) of the stated amounts of Levocetirizine Hydrochloride	97.75 %
8	Uniformity of content	85 % to 115 % of stated amount of Montelukast	97.55 % to 99.25 %
9	Uniformity of content	85 % to 115 % of stated amount of Levocetirizine Hydrochloride	98.74 % to 111.94 %
10	Related substances	Montelukast Sulphoxide: NMT- 2.0 %	0.54 %
11	Related substances	Montelukast Styrene: NMT- 1.0 %	0.21 %
12	Related substances	Any other impurity: NMT-1.0 %	0.26 %
13	Related substances	Sum of all impurities: NMT-4.0 %	0.69 %
14	Assay Each film coated tablet contains	-	-
15	Montelukast sodium IP Eq. to Montelukast 10 mg	NLT 90.0% and NMT 110.0% of the labeled amount	101.90 %
16	Levocetirizine Hydrochloride IP 5 mg	NLT 90.0% and NMT 110.0% of the labeled amount	100.59 %

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

Particulars	Prepared By	Checked By	Approved By
Sign & Date	14/10/2026	14/10/2026	14/10/2026
Name:	VINOD SAINI	JAGJEET SINGH	ALOK SINGH
Designation:	Q.C Executive	Sr. Q.C Executive	Q.C Manager