



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Montaheal-10	A.R. No.	FG/G/24A1260
Generic Name	Montelukast Tablets IP 10 mg	Sample Quantity	75 Tablets
Batch No.:	AGT40885	Sample Received on	09/09/2024
Batch Size:	1.50 Lac	Analysis Date	09/09/2024
Mfg. Date.	08/2024	Release Date	19/09/2024
Exp. Date	07/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Yellow colour, round shaped, biconvex, having both side plain, film coated tablet.	Yellow colour, round shaped, biconvex, having both side plain, film coated tablet.		
2.	Identification	The principal peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution as obtained in assay.	Complies		
3.	Average weight	174.00 mg $\pm$ 3%	177.74 mg		
4.	Uniformity of weight	$\pm$ 7.5% of its average weight.	Min: 173.65 mg ; Max: 181.50 mg -2.30% ; +2.12%		
5.	Disintegration	Not more than 30 minutes.	05 minutes 25 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	7.25 Kg/cm ²		
7.	Dissolution	Not less than 70.00% (Q)	Minimum = 94.21% Maximum = 100.07% Average = 97.76%		
8.	Uniformity of content	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	1.59		
9.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Montelukast Sodium IP Eq. to Montelukast	10 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 9.0 mg to 11.0 mg)	9.860 mg	98.60 %
10.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		50 cfu/g	
ii.	Total yeast and mould count	NMT 100 cfu/g		Less than 10 cfu/g	
iii.	Pathogens: Escherichia coli	Should be absent/g		Absent/g	

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Shashi Kumar
Designation	Executive	Sr. Executive	Manager-QA
Signature			
Date	19/09/2024	19/09/2024	19/09/2024