



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/24A0185
Generic Name	Montelukast Tablets IP 10 mg	Sample Quantity	120 Tablets
Batch No.:	AGT40268	Sample Received on	11/03/2024
Batch Size:	1.50 Lac	Analysis Date	11/03/2024
Mfg. Date.	02/2024	Release Date	16/03/2024
Exp. Date	01/2027	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 ± 3%	178.798 mg		
4.	Uniformity of weight	± 7.5% of its average weight.	Min: 176.65 mg ; Max: 181.57 mg -1.20% ; +1.55%		
5.	Disintegration	Not more than 30 minutes.	06 minutes 16 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	7.3 Kg/cm ²		
7.	Dissolution	Not less than 70.00% (Q)	Minimum = 90.67% Maximum = 98.67% Average = 95.78%		
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)	11.54		
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)	9.9769 mg	99.77 %
10.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		25 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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	16/03/2024	16/03/2024	16/03/2024