



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Acecloheal-MR	A.R. No.	FG/G/24A0214
Generic Name	Aceclofenac, Paracetamol & Chlorzoxazone Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40317	Sample Received on	19/03/2024
Batch Size:	5.0 Lac	Analysis Date	19/03/2024
Mfg. Date.	03/2024	Release Date	28/03/2024
Exp. Date	02/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Orange colour, elongated, biconvex having scored line on one side and other side plain, film coated tablet.	Orange colour, elongated, biconvex having scored line on one side and other side plain, film coated tablet.		
2.	Identification	In the assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	925.00 mg $\pm$ 3.0%.	926.748 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 913.82 mg ; Max: 934.62 mg - 1.40% ; + 0.85%		
5.	Disintegration	Not more than 30 minutes.	09 minutes 47 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	12.5 Kg/cm ²		
7.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Aceclofenac IP	100 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 90.0 mg to 110.0 mg)	103.42 mg	103.42%
	Paracetamol IP	325 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 292.5 mg to 357.5 mg)	327.259 mg	100.70%
	Chlorzoxazone USP	250 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 225.0 mg to 275.0 mg)	254.371 mg	101.75%
8.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		35 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	Gauram Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	28/03/2024	28/03/2024	28/03/2024