



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-SP	A.R. No.	FG/G/24A0099
Generic Name	Aceclofenac, Paracetamol & Serratiopeptidase Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40129	Sample Received on	06/02/2024
Batch Size:	5.0 Lac	Analysis Date	06/02/2024
Mfg. Date.	01/2024	Release Date	12/02/2024
Exp. Date	12/2025	Page No.:	Page 1 of 1

3Sr.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red colour, elongated, biconvex having scored line on one side and other side plain, film coated tablet.	Brick red colour, elongated, biconvex having scored line on one side and other side plain, film coated tablet.		
2.	Identification	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.	Complies		
3.	Average weight	657.0 mg ± 3%	662.289 mg		
4.	Uniformity of weight	± 5% of its average weight.	Min: 656.18 mg ; Max: 667.95 mg -0.92% ; +0.85%		
5.	Disintegration	Not more than 30 minutes.	05 minutes 31 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	16.5 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	98.11 mg	98.11%
	Paracetamol IP	325 mg	Between 90.0 % to 110.0 % of labeled amount. Between 292.5 mg to 357.5 mg	320.150 mg	98.51%
	Serratiopeptidase IP (As enteric coated granules)	15 mg	Not less than 90.0 % (Not less than 13.5 mg)	17.45 mg	116.33%
8.	Microbial Limit Tests:				
a.	Total aerobic microbial count	NMT 1000 cfu/g	30 cfu/g		
b.	Total yeast and mould count	NMT 100 cfu/g	Less than 10 cfu/g		
c.	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	Braveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	12/02/2024	12/02/2024	12/02/2024