



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/23A1091
Generic Name	Acceclofenac, Paracetamol & Serratiopeptidase Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT31276	Sample Received on	23/12/2023
Batch Size:	5.0 Lac	Analysis Date	23/12/2023
Mfg. Date.	12/2023	Release Date	01/01/2024
Exp. Date	11/2025	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red colour, elongated, biconvex having scored line on one side, film coated tablet.	Brick red colour, elongated, biconvex having scored line on one side, film coated tablet.		
2.	Identification (By HPLC)	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%	662.435 mg		
4.	Uniformity of weight	± 5% of its average weight.	Min: 646.32 mg ; Max: 670.43 mg -2.43% ; +1.21%		
5.	Disintegration	Not more than 30 minutes.	07 minutes 17 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	11.67 Kg/cm ²		
7.	Assay (By HPLC):				
	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	95.609 mg	95.61%
	Paracetamol IP	325 mg	Between 90.0 % to 110.0 % of labeled amount. Between 292.5 mg to 357.5 mg	314.844 mg	96.88%
	Serratlopeptidase IP (As enteric coated granules)	15 mg	Not less than 90.0 % (Not less than 13.5 mg)	17.781 mg	118.54%
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	Karamjit Kaur	Tanvej	Ravishankar Singh
Designation	QC Officer	Sr. Executive	Head - QA
Signature			
Date	01/01/2024	01/01/2024	01/01/2024