

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Acecloheal- Plus	A.R. No.	FG/G/24A1611
Generic Name	Aceclofenac and Paracetamol Tablets IP	Sample Quantity	60 Tablets
Batch No.:	AGT41183A	Sample Received on	05/12/2024
Batch Size:	1.50 Lac	Analysis Date	05/12/2024
Mfg. Date.	11/2024	Release Date	11/12/2024
Exp. Date	10/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Yellow colour, 'elongated shaped, biconvex, having both side plain, film coated tablet.	Yellow colour, elongated shaped, biconvex, having both 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 (c).	Complies		
3.	Average weight	720.50 mg $\pm$ 3%	711.13 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 703.33 mg ; Max: 717.24 mg -1.10% ; +0.86%		
5.	Disintegration time	Not more than 30 minutes.	03 minutes 52 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	15.75 Kg/cm ²		
7.	Dissolution:				
	For Aceclofenac	Not less than 70.0 % (Q)	Min. 93.73%, Max. 99.60%		
	For Paracetamol	Not less than 70.0 % (Q)	Min. 96.01%, Max. 100.05%		
8.	Related Substances:				
	Aceclofenac impurity A	Not more than 5.0%	Not Detected		
	4-aminophenol	Not more than 0.1%	Not Detected		
	4-chloroacetanilide	Not more than 0.05%	Not Detected		
	Any secondary impurity	Not more than 0.5%	Not Detected		
	Total impurities	Not more than 2.0%	Not Detected		
9.	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	98.48 mg	98.48%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	11/12/2024	11/12/2024	11/12/2024



ALVENTA PHARMA LIMITED

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

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Sr. No.	Test Parameter	Acceptance Criteria		Result	
	Paracetamol IP	325 mg	Between 90.0 % to 110.0 % of labeled amount. Between 292.5 mg to 357.5 mg	315.653 mg	97.12%
10.	Microbial Limit Tests:				
a.	Total aerobic microbial count	NMT 1000 cfu/g		45 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.

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