

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Acecloheal-TH	A.R. No.	FG/G/24A1141
Generic Name	Aceclofenac, Paracetamol & Thiocolchicoside Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40691	Sample Received on	07/08/2024
Batch Size:	1.0 Lac	Analysis Date	07/08/2024
Mfg. Date.	06/2024	Release Date	12/08/2024
Exp. Date	05/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Yellow colour, elongated shaped, biconvex, having scored line on one side, film coated tablet.	Yellow colour, elongated shaped, biconvex, having scored line on one side, 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%	927.864 mg
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 906.30 mg ; Max: 948.02 mg -2.32% ; +2.17%
5.	Disintegration time	Not more than 30 minutes.	04 minutes 33 seconds.
6.	Hardness	NLT 4.0 Kg/cm ²	17.83 Kg/cm ²
7.	Assay:		
	Each film coated tablet contains:	Claim	Limit
	Aceclofenac IP	100 mg	Between 90.0 % to 110.0 % of labeled amount. Between 90.0 mg to 110.0 mg
	Paracetamol IP	325 mg	Between 90.0 % to 110.0 % of labeled amount. Between 292.5 mg to 357.5 mg
	Thiocolchicoside IP	4 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 3.6 mg to 4.4 mg)
9.	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	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	12/08/2024	12/08/2024	12/08/2024