

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Ursodec-150	A.R. No.	FG/G/24A1349
Generic Name	Ursodeoxycholic Acid Tablets IP 150 mg	Sample Quantity	90 Tablets
Batch No.:	AGT40987	Sample Received on	28/09/2024
Batch Size:	1.50 Lac	Analysis Date	28/09/2024
Mfg. Date.	09/2024	Release Date	05/10/2024
Exp. Date	08/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Brick Red colour, round shaped, biconvex, having both side plain, film coated tablet.	Brick Red colour, round shaped, biconvex, having both side plain, film coated tablet.
2.	Identification	In the assay, the retention time of 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	360.50 mg $\pm$ 3%	360.76 mg
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 350.38 mg ; Max: 370.21 mg -2.96 % ; +2.62 %
5.	Disintegration	Not more than 30 minutes.	01 minutes 55 seconds.
6.	Hardness	NLT 4.0 Kg/cm ²	6.41 Kg/cm ²
7.	Dissolution	Not less than 75.0 % (Q)	Minimum = 99.80 % Maximum = 102.62 % Average = 101.19 %
8.	Assay:		
	Each film coated tablet contains:	Claim	Limit
	Ursodeoxycholic Acid IP	150 mg	Between 92.5 % to 107.5 % of stated amount (Between 138.75 mg to 161.25 mg)
			mg
			%
9.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	40 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	Ankur Kumar	Shashi Kumar
Designation	Executive	Executive	Manager QA
Signature			
Date	05/10/2024	05/10/2024	05/10/2024