



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Ursodec-300	A.R. No.	FG/G/24A1029
Generic Name	Ursodeoxycholic Acid Tablets IP 300 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40734C	Sample Received on	15/07/2024
Batch Size:	0.75 Lac	Analysis Date	15/07/2024
Mfg. Date.	07/2024	Release Date	25/07/2024
Exp. Date	06/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, elongated, biconvex, having one side plain and other side three line scored, film coated tablet.	White colour, elongated, biconvex, having one side plain and other side three line scored, film coated tablet.		
2.	Identification:				
	a) By IR	The spectrum of the residue in the sample should match with spectrum obtained with Ursodeoxycholic acid working or reference standard or with the reference spectrum of Ursodeoxycholic acid.	Complies		
	b) By HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	472.00 mg $\pm$ 3%	470.994 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 460.70 mg ; Max: 475.97 mg -1.06% ; +2.19%		
5.	Disintegration	Not more than 30 minutes.	04 minutes 45 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	6.25 Kg/cm ²		
7.	Dissolution	Not less than 75.00% (Q)	Min. = 87.07% Max. = 91.98% Mean = 88.48%		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Ursodeoxycholic Acid IP	300 mg	Between 92.5 % to 107.5 % of stated amount (Between 277.5 mg to 322.5 mg)	297.56 mg	99.19%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	25/07/2024	25/07/2024	25/07/2024



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9.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	35 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.

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Name	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	25/07/2024	25/07/2024	25/07/2024