



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Febutop-40	A.R. No.	FG/G/24A0998
Generic Name	Febuxostat Tablets 40 mg	Sample Quantity	120 Tablets
Batch No.:	AGT40714	Sample Received on	08/07/2024
Batch Size:	2.0 Lac	Analysis Date	08/07/2024
Mfg. Date.	07/2024	Release Date	20/07/2024
Exp. Date	06/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Yellow colour, round shaped, biconvex, both side plain, film coated tablet.	Yellow colour, round shaped, biconvex, 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	174.00 mg $\pm$ 3%	173.481 mg		
4.	Uniformity of weight	$\pm$ 7.5% of its average weight.	Min: 169.81 mg ; Max: 177.95 mg - 2.12% ; + 2.58%		
5.	Disintegration	Not more than 30 minutes.	03 minutes 47 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	5.58 Kg/cm ²		
7.	Dissolution	Not less than 70.00% (Q)	Minimum = 91.97% Maximum = 100.08% Average = 96.36%		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Febuxostat	40 mg	Between 90.0 % to 110.0 % of stated amount (Between 36.0 mg to 44.0 mg)	39.366 mg	98.42%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		30 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	DURGESH KUMAR	Gautam Singh
Designation	Executive	Ag Head	Head QA
Signature			
Date	20/07/2024	20/07/2024	20/07/2024