



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/24A0386
Generic Name	Febuxostat Tablets 40 mg	Sample Quantity	120 Tablets
Batch No.:	AGT404110	Sample Received on	13/05/2024
Batch Size:	2.0 Lac	Analysis Date	13/05/2024
Mfg. Date.	04/2024	Release Date	20/05/2024
Exp. Date	03/2027	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 ± 3%	175.229 mg		
4.	Uniformity of weight	± 7.5% of its average weight.	Min: 171.47 mg ; Max: 179.11 mg - 2.15% ; + 2.22%		
5.	Disintegration	Not more than 30 minutes.	02 minutes 10 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	5.36 Kg/cm ²		
7.	Dissolution	Not less than 70.00% (Q)	Minimum = 89.52% Maximum = 90.09% Average = 89.73%		
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)	38.961 mg	97.40%
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.

Particulars	Prepared By	Checked By	Approved By
Name	Harveen Kumar	DURGESH KUMAR	Gaution Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	20/05/2024	20/05/2024	20/05/2024