



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-80	A.R. No.	FG/G/24A0188
Generic Name	Febuxostat Tablets 80 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40287	Sample Received on	12/03/2024
Batch Size:	1.0 Lac	Analysis Date	12/03/2024
Mfg. Date.	02/2024	Release Date	18/03/2024
Exp. Date	01/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Green colour, round shaped, biconvex, both side plain, film coated tablet.	Green 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%	175.863 mg		
4.	Uniformity of weight	$\pm$ 7.5% of its average weight.	Min: 173.48 mg ; Max: 177.92 mg - 1.36% ; + 1.17%		
5.	Disintegration	Not more than 30 minutes.	04 minutes 16 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	10.5 Kg/cm ²		
7.	Dissolution	Not less than 70.00% (Q)	Minimum = 85.55% Maximum = 95.31% Average = 90.84%		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Febuxostat	80 mg	Between 90.0 % to 110.0 % of stated amount (Between 72.0 mg to 88.0 mg)	79.943 mg	99.93%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		25 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	QC Head	Head-QA
Signature			
Date	18/03/2024	18/03/2024	18/03/2024