



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Lefuheal-10	A.R. No.	FG/G/24A1489
Generic Name	Leflunomide Tablets IP 10 mg	Sample Quantity	60 Tablets
Batch No.	AGT41094	Sample Received on	08/11/2024
Batch Size	1.0 Lac	Analysis Date	08/11/2024
Mfg. Date	10/2024	Release Date	13/11/2024
Exp. Date	09/2026	Page No.	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, round shaped, biconvex having both side plain, film coated tablet.	White colour, round shaped, biconvex, having both side plain, film coated tablet.		
2.	Identification:				
	a) By UV	When examined in the range 220 nm to 360 nm, a 0.001 per cent w/v solution in methanol shows an absorption maximum similar to that of Leflunomide IPRS.	Complies		
	b) By HPLC	In the Assay, 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	265.00 mg $\pm$ 3.0%.	268.47 mg		
4.	Uniformity of weight	$\pm$ 5.0% of its average weight.	Min: 258.75 mg ; Max: 274.25 mg -3.76% ; +2.15%		
5.	Disintegration	Not more than 30 minutes.	00 minutes 50 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	7.91 Kg/cm ²		
7.	Dissolution	Not less than 70.00 % (Q) of the labeled amount is dissolved in 30 minutes.	Minimum = 92.22% Maximum = 97.94% Average = 94.71%		
8.	Uniformity of content	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	8.44		
9.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Leflunomide IP	10 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 9.0 mg to 11.0 mg)	9.963 mg	99.63%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	RamAwadh Yadav
Designation	Executive	Head QC	Head QA
Signature			
Date	13/11/2024	13/11/2024	13/11/2024



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10.	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	Praveen Kumar	Kuljeet Kaur	RamAwadh Yadav
Designation	Executive	Head QC	Head QA
Signature			
Date	13/11/2024	13/11/2024	13/11/2024