

Quality Control Department
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Lefuheal-10	A.R. No.	FG/G/24A0268
Generic Name	Leflunomide Tablets IP 10 mg	Sample Quantity	60 Tablets
Batch No.	AGT40392	Sample Received on	06/04/2024
Batch Size	1.0 Lac	Analysis Date	06/04/2024
Mfg. Date	03/2024	Release Date	13/04/2024
Exp. Date	02/2026	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%.	259.08 mg
4.	Uniformity of weight	$\pm$ 5.0% of its average weight.	Min: 251.15 mg ; Max: 265.74 mg -3.06% ; +2.57%
5.	Disintegration	Not more than 30 minutes.	01 minutes 20 seconds.
6.	Hardness	Not less than 4.0 Kg/cm ²	10.6 Kg/cm ²
7.	Dissolution	Not less than 70.00 % (Q) of the labeled amount is dissolved in 30 minutes.	Minimum = 82.59% Maximum = 87.02% Average = 84.97%
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)	1.75
9.	Assay:		
	Each film coated tablet contains:	Claim	Limit
	Leflunomide IP	10 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 9.0 mg to 11.0 mg)
			mg %
			9.726 mg 97.26%

Particulars	Prepared By	Checked By	Approved By
Name	Braveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head QA
Signature			
Date	13/04/2024	13/04/2024	13/04/2024



ALVENTA PHARMA LIMITED

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

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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	DURGESH KUMAR	Anurag Singh
Designation	Executive	QC Head	Head QA
Signature			
Date	13/04/2024	13/04/2024	13/04/2024