



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Levecan-500	A.R. No.	FG/G/24A1436
Generic Name	Levetiracetam Tablets IP 500 mg	Sample Quantity	60 Tablets
Batch No.:	AGT41043B	Sample Received on	19/10/2024
Batch Size:	2.0 Lac ✓	Analysis Date	19/10/2024
Mfg. Date.	10/2024	Release Date	25/10/2024
Exp. Date	09/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Yellow colour, elongated shaped, biconvex, having scored line on one side and other side plain, film coated tablet.	Yellow colour, elongated shaped, biconvex, having scored line on one side and other side plain, film coated tablet.		
2.	Identification:				
	A. By IR	The bands in the region of 650-3800 cm^{-1} obtained for test sample correspond to the bands obtained for Levetiracetam working standard.	Complies		
	B. By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution should be corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	765.00 mg \pm 3%	766.73 mg ✓		
4.	Uniformity of weight	\pm 5% of its average weight.	Min: 744.09 mg ; Max: 783.03 mg - 3.04% ; +2.13% ✓		
5.	Disintegration	Not more than 30 minutes.	08 minutes 25 seconds. ✓		
6.	Hardness	NLT 4.0 Kg/cm ²	12.75 Kg/cm ² ✓		
7.	Dissolution	Not less than 80.0% (Q)	Minimum = 89.91% Maximum = 92.25% Average = 91.53%		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Levetiracetam IP	500 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 450.0 mg to 550.0 mg)	490.7426 mg	98.15%
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	Praveen Kumar	Kuljeet Kaur	Balprekash Singh
Designation	Executive	Head QC	Plant Head
Signature			
Date	25/10/2024	25/10/2024	25/10/2024