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/25A0843
Generic Name	Levetiracetam Tablets IP 500 mg	**Sample Quantity**	60 Tablets
Batch No.:	AGT50573	**Sample Received on**	01/06/2025
Batch Size:	2.0 Lac	**Analysis Date**	01/06/2025
Mfg. Date.	05/2025	**Release Date**	07/06/2025
Exp. Date	04/2028	**Page No.:**	Page 1 of 2

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 ± 3%	761.05 mg
4.	**Uniformity of weight**	± 5% of its average weight.	Min: 745.15 mg ; Max: 777.89 mg - 2.09% ; +2.21%
5.	**Disintegration**	Not more than 30 minutes.	07 minutes 12 seconds.
6.	**Hardness**	NLT 4.0 Kg/cm^2	11.75 Kg/cm^2
7.	**Dissolution**	Not less than 80.0% (Q)	Minimum = 95.45% Maximum = 101.09% Average = 98.19%
8.	**Related Substances:**		
	Levetiracetam acid	Not more than 0.3%	Not Detected
	Any secondary impurity	Not more than 0.1%	Not Detected
	Total impurities	Not more than 0.6%	Not Detected

9.	**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)	510.04 mg	102.01%

Particulars	Prepared By	Checked By	Approved By
Name	Barun Kumar	Kamal Kant	Kuljeet Kaur
Designation	Executive	Executive	Head QC
Signature			
Date	07/06/2025	07/06/2025	07/06/2025

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10.	**Microbial Limit Tests:**		
i.	**Total aerobic microbial count**	NMT 1000 cfu/g	30 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	Kamey Kaur	Tulsi Ram
Designation	Executive	Executive	Head QC
Signature			
Date	07/06/2025	07/06/2025	07/06/2025