



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Gabatop-NT	A.R. No.	FG/G/24A1028
Generic Name	Gabapentin & Nortriptyline Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40719	Sample Received on	15/07/2024
Batch Size:	1.0 Lac	Analysis Date	15/07/2024
Mfg. Date.	07/2024	Release Date	25/07/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, elongated shaped, biconvex, scored line on one side and other side plain, film coated tablet.	White colour, elongated shaped, biconvex, scored line on one side and other side plain, film coated tablet.		
2.	Identification	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	509.00 mg ± 3%	513.391 mg		
4.	Uniformity of weight	± 5% of its average weight.	Min: 499.85 mg ; Max: 520.95 mg - 2.64% ; +1.47%		
5.	Disintegration	Not more than 30 minutes.	05 minutes 05 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	7.17 Kg/cm ²		
7.	Uniformity of content (For Nortriptyline HCl)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	1.05		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Gabapentin IP	400 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 360.0 mg to 440.0 mg)	408.272 mg	102.07%
	Nortriptyline Hydrochloride IP Eq. to Nortriptyline	10 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 9.0 mg to 11.0 mg)	9.9272 mg	99.27%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		40 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	

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	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	25/07/2024	25/07/2024	25/07/2024