



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Pregarica-NT	A.R. No.	FG/G/24A0437
Generic Name	Pregabalin & Nortriptyline Tablets	Sample Quantity	100 Tablets
Batch No.	AGT40564	Sample Received on	26/05/2024
Batch Size	1.10 Lac	Analysis Date	26/05/2024
Mfg. Date.	05/2024	Release Date	02/06/2024
Exp. Date.	04/2026	Page No.:	Page 1 of 1

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	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%	266.18 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 258.55 mg ; Max: 271.66 mg -2.95% ; +2.06%		
5.	Disintegration	Not more than 30 minutes.	05 minutes 12 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	6.25 Kg/cm ²		
7.	Uniformity of content (For Nortriptyline)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	2.43		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Pregabalin IP	75 mg	Between 90.0 % to 110.0 % of labeled amount. Between 67.5 mg to 82.5 mg	74.74 mg	99.66%
	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	9.8869 mg	98.87%
9.	Microbial Limit Tests:				
a.	Total aerobic microbial count	NMT 1000 cfu/g		30 cfu/g	
b.	Total yeast and mould count	NMT 100 cfu/g		Less than 10 cfu/g	
c.	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	BURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	02/06/2024	02/06/2024	02/06/2024