



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-Triple	A.R. No.	FG/G/24A0201
Generic Name	Pregabalin, Nortriptyline & Methylcobalamin Tablets	Sample Quantity	100 Tablets
Batch No.	AGT40289	Sample Received on	15/03/2024
Batch Size	1.0 Lac	Analysis Date	15/03/2024
Mfg. Date.	02/2024	Release Date	21/03/2024
Exp. Date.	01/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red colour, round shaped, biconvex having both side plain, film coated tablet.	Brick red 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 ± 3%	265.33 mg		
4.	Uniformity of weight	± 5% of its average weight.	Min: 260.86 mg ; Max: 268.65 mg -1.69% ; +1.25%		
5.	Disintegration	Not more than 30 minutes.	04 minutes 10 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	7.3 Kg/cm ²		
7.	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)	74.707 mg	99.61%
	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)	9.796 mg	97.96%
	Methylcobalamin IP	1500 mcg	Not less than 90.0% (Not less than 1350 mcg)	1889.66 mcg	125.98%
8.	Microbial Limit Tests:				
a.	Total aerobic microbial count	NMT 1000 cfu/g		35 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	Tanvej	Gaurav Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	21/03/2024	21/03/2024	21/03/2024