FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	PREGABALIN USP		
Batch No.	PG/26/001		
Release Date	15/01/2026	**Batch Size**	611.130 Kg
Mfg. Date	January - 2026	**Retest Date**	December - 2029

Sr. No.	TESTS	SPECIFICATION	RESULT
01	Description	A White to off-white crystalline Solid	A White crystalline Solid.
02	Solubility	Freely Soluble in water and in both basic and acidic aqueous Solution.	Freely Soluble in water and in both basic and acidic aqueous Solution.
03	Identification		
	(1) By IR	The IR absorption spectrum of the sample must be concordant with that of similar preparation of Pregabalin standard.	Complies
	(2) By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in Assay	Complies
04	Assay By HPLC (ODB)	98.0% to 102.0%, Calculated on dried basis	99.84%
05	Residue on ignition	Not more than 0.1%	0.02%
06	Chlorine and Sulfate	The turbidity produced in the sample solution is not more than that produced in the standard solution (0.1%)	Complies
07	Organic impurities by HPLC		
	Mandelic acid	Not more than 0.10%	0.022%
	Isobutylglutaric acid	Not more than 0.15%	Not Detected
	Isobutylglutarmonomide	Not more than 0.15%	0.019%

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Sr. No.	**TESTS**	**SPECIFICATION**	**RESULT**
	Pregabalin Related compound C	Not more than 0.15%	Not Detected
	Any unspecified impurity	Not more than 0.10%	0.070%
	Total impurity	Not more than 0.80%	0.259%
08	Enantiomeric Purity	Not more than 0.15%	0.04%
09	Loss on Drying	Not more than 0.5%	0.19%
Additional Test			
10	Residual Solvent By GC		
	Isopropyl Alcohol	Not more than 5000 ppm	120 ppm
	Chloroform	Not more than 60 ppm	Not Detected

Remarks: - The product complies / ~~does not complies~~ as per USP specification.