



SARACA LABORATORIES LIMITED

MANUFACTURERS OF BASIC DRUGS & INTERMEDIATES

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METAPHARMACEUTICAL

N DE LOTE:

028032S

25/03/2025

CERTIFICATE OF ANALYSIS

Format No.: SOP/QC/GEN-008/F-001/01

Name of the Product	GABAPENTIN	Reference	Ph.Eur
Batch No.	GP/02 2025 0037	Date of Manufacture	February – 2025
Dispatch Quantity	75 Kg	Date of Re-Test	January – 2029
A.R.No.	GP/25/02/0038	Date of Analysis	20-02-2025
Manufactured by	Saraca Laboratories Limited, Unit-I		

S. No.	TEST	SPECIFICATION	RESULT
1.	Appearance	White or almost white crystalline powder	Almost white crystalline powder
2.	Solubility	Sparingly soluble in water, slightly soluble in (96%) ethanol, practically in soluble in methylene chloride It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Complies
3.	IDENTIFICATION		
	A. Infrared absorption spectrophotometer	The sample and standard IR spectrum of mineral oil dispersion should be concordant.	Positive
	B. Appearance of solution	The solution is clear and colorless	Complies
4.	pH	6.5 to 7.5	7.01
5.	Related substance (by HPLC)	Test A	
		Impurity A	NMT 0.15 %w/w
		Any unspecified impurity	NMT 0.10 %w/w
		Test B	
		Any unspecified impurity	NMT 0.05 %w/w
		Total impurities (Including test A and test B)	NMT 0.5 %w/w
6.	Chlorides	Maximum 100 ppm	ND
7.	Water content	Maximum 0.3%	0.0099 %w/w
8.	Sulfated ash	Maximum 0.1%	0.039 %w/w
9.	Assay by HPLC (anhydrous basis)	97.5%w/w to 102.0%w/w	99.9 %w/w
10.	Residual solvents	Methanol	NMT 3000 ppm
		Isopropyl alcohol	NMT 5000 ppm
		Acetone	NMT 5000 ppm
		Ethyl acetate	NMT 5000 ppm

Abbreviations:- ND: Not Detected, BDL : Below Detectable Limit, NMT : Not More Than, NLT: Not Less Than.

Opinion of analysis: The product **complies** as per the above specifications.

Compiled by		Checked by		Approved by	
Date	21/02/25	Date	21/02/25	Date	21/02/25

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