

Date: 19/03/2022

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CERTIFICATE OF ANALYSIS

PRODUCT : GABAPENTIN

DATE OF MFG. : FEB – 2022

BATCH No. : B71010622/043

RETEST DATE : JAN – 2026

A.R. No. : FP220449

DATE OF ANALYSIS : 28/02/2022

QUANTITY : 2 x 25 Kg

TEST PARAMETERS	RESULTS	SPECIFICATIONS
Appearance	White crystalline powder	White or almost white crystalline powder ✓
Solubility	Complies	Sparingly soluble in water, slightly soluble in ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides. ✓
Identification		
By IR spectrum	Complies	To comply with the standard IR spectrum ✓
Appearance of solution	Complies	The solution is clear and colourless ✓
pH	7.0	6.8 – 7.4 ✓
Water	0.03%	Not more than 0.2% w/w ✓
Sulphated ash	0.03%	Not more than 0.1% w/w ✓
Chloride	25 ppm	Not more than 100 ppm ✓
Assay (On anhydrous basis)	99.7 %	98.7% to 101.0% w/w ✓
The material complies with Current EP specification		

Nº lote ACOFARMA:

222320

Firma y fecha:

22/02/22

PREPARED BY QA

DATE: 19/03/2022

CHECKED BY QC:

DATE: 19/03/2022

APPROVED BY QA:

DATE: 19/03/2022

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TEST PARAMETERS	RESULTS	SPECIFICATIONS
Related substance test A (By HPLC)		
A. Early eluting impurities		
Impurity A	0.01%	Not more than 0.05%
Gabapentin related compound B	Not detected	Not more than 0.05%
Gabapentin related compound E	Not detected	Not more than 0.05%
Individual unknown impurity	0.01%	Not more than 0.05%
Related substance test B (By HPLC)		
Gabapentin related compound D	Not detected	Not more than 0.05%
Any other impurity	Not detected	Not more than 0.05%
Total related compounds (Related substances test A +B)	0.04%	Not more than 0.30%
# Residual solvents		
Methanol	BLD*	Not more than 250 ppm
Isopropanol	35 ppm	Not more than 1000 ppm
Acetone	BLD*	Not more than 100 ppm
Toluene	Not detected	Not more than 100 ppm
The material complies with current EP & # In house specifications		

BLD* - Below Limit of Detection.

Nº lote ACOFARMA:

222320

Firma y fecha:

22/04/22

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