HIKAL

Date: 04/03/2022

CERTIFICATE OF ANALYSIS

PRODUCT : GABAPENTIN
BATCH No. : G71010622/075
A.R.No. : FP220305

DATE OF MFG. : FEB – 2022
RETEST DATE : JAN – 2026
DATE OF ANALYSIS : 11/02/2022

TEST PARAMETERS	RESULTS	SPECIFICATIONS
Description	White crystalline powder	White to off- white crystalline powder
Solubility	Complies	Freely soluble in water and in alkaline and acidic solutions.
Identification A) By IR spectrum	Complies	To comply with the standard IR spectrum
B) By HPLC	Complies	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in chromatogram of standard preparation, as obtained in assay
pH (1 in 50 aqueous solution)	7.3	Between 6.8 - 7.4
Water (Karl Fisher)	0.03%	Not more than 0.2%w/w
Residue on ignition	0.02%	Not more than 0.1%w/w
# Limit of Chloride (By Potentiometry)	0.0028%	Not more than 0.01%.
# Solubility	Complies	Sparingly soluble in methanol
# Colour and clarity of the solution	Complies	The solution in water is clear and colourless
The material complies with Current USP and # In house specifications		

PREPARED BY QA: **DATE: 04/03/2022**

CHECKED BY QC: **DATE: 04/03/2022**

APPROVED BY QA: **DATE: 04/03/2022**

Hikal Ltd.

Factory Unit I: 82/A, KIADB Indl. Area, Jigani, Anekal Taluk, Bangalore – 560 105, India. Tel.: +91-80-3986 1100, +91-8110-421100. Fax: +91-80-2782 5378

Admin. Office: Great Eastern Chambers, 6th Floor, Sector 11, CBD Belapur, Navi Mumbai - 400 614, India.Tel. : +91-22-3097 3100. Fax : +91-22-2757 4277

Regd. Office: 717, Maker Chamber - 5, Nariman Point, Mumbai - 400 021, India, Tel. : +91-22-3926 7100, +91-22-6630 1801. Fax : +91-22-22833913

www.hikal.com info@hikal.com CIN: L24200MH1988PTC048028

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PRODUCT	**: GABAPENTIN**	**DATE OF MFG.**	**: FEB – 2022**
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TEST PARAMETERS	RESULTS	SPECIFICATIONS
Assay (On anhydrous basis) and early eluting impurities (By HPLC)		
Assay (On anhydrous basis)	100.0%	98.0 to 102.0% w/w
Early eluting impurities (By HPLC)		
Gabapentin related compound A	0.01%	Not more than 0.10%
Gabapentin related compound B	Not detected	Not more than 0.06%
Gabapentin related compound E	Not detected	Not more than 0.10%
Individual unknown impurity	0.01%	Not more than 0.05%
Late eluting impurities (By HPLC)		
Gabapentin related compound D	Not detected	Not more than 0.10%
Any other impurity	Not detected	Not more than 0.05%
Total related compounds (Including early eluting impurities)	0.03%	Not more than 0.50% w/w
# Residual solvents		
Methanol	86 ppm	Not more than 250 ppm
Isopropanol	163 ppm	Not more than 1000 ppm
Acetone	BLD*	Not more than 100 ppm
Toluene	BLD*	Not more than 100 ppm
The material complies with Current USP & # In house specifications		

BLD * - Below limit of detection.

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