KalChem INTERNATIONAL
Compounding Chemicals You Can Trust

HIKAL

Date: 04/09/2024

CERTIFICATE OF ANALYSIS

PRODUCT : GABAPENTIN
BATCH No. : G71010624/443
A.R.No. : FP242266

DATE OF MFG. : AUG – 2024
RETEST DATE : JUL – 2028
DATE OF ANALYSIS : 02/09/2024
QUANTITY : 12 x 25 Kg

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)	7.1	Between 6.8 - 7.4
Water (Karl Fisher)	0.05%	Not more than 0.2%w/w
Residue on ignition	0.03%	Not more than 0.1%w/w
# Limit of Chloride (By Potentiometry)	0.0013%	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: 04/09/2024

CHECKED BY QC:
DATE: 04/09/2024

APPROVED BY QA:
DATE: 04/09/2024

Hikal Ltd.

Factory Unit I : 82/A & 72, KIADB Industrial Area, Jigani, Anekal Taluk, Bangaluru (Bangalore) Karnataka – 560 105, India. Tel. : +91-8110-421100

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TEST PARAMETERS	RESULTS	SPECIFICATIONS
Assay (On anhydrous basis) and early eluting impurities (By HPLC)		
Assay (On anhydrous basis)	99.9%	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	69 ppm	Not more than 250 ppm
Isopropanol	129 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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