METAPHARMACEUTICAL

N DE LOTE: 0060422

11/04/2022

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CERTIFICATE OF ANALYSIS

CA.3099/020/19

Product name:	**GABAPENTIN**	**CAS Number:**	[60142-96-3]
Chemical name:	1-(Aminomethyl)cyclohexaneacetic acid		
Molec.Formula:	$C_9H_{17}NO_2$	**Molec.Weight:**	171.24
Batch Nº:	3099/11439		
Date of Manufacture:	DEC-2021	**Retest Date:**	NOV-2026

TESTS	SPECIFICATIONS	RESULTS
Appearance	White to off-white crystalline powder.	Complies
Solubility	Freely soluble in water. Sparingly soluble in methanol. Practically insoluble in acetone and methylene chloride.	Complies
Identification		
Infrared Absorption	Matches with the *USP Gabapentin RS*.	Complies
HPLC Retention time	Matches with the *Standard preparation* as obtained in the *Assay*.	Complies
Loss on drying	Not more than 0.5%.	0.03%
pH	Between 6.5 and 8.0, in a solution (1 in 50).	6.9
Water (KF)	Not more than 0.5%.	0.04%
Sulphated ash	Not more than 0.1%.	0.06%
Particle size	More than 90% passes through 400 microns.	Complies
Related compounds (HPLC)		
Limit of early eluting impurities:		
Gabapentin related compound E	Not more than 0.10%.	<0.01%
Gabapentin related compound A	Not more than 0.05%.	0.01%
Gabapentin related compound B	Not more than 0.06%.	<0.02%
Individual unknown impurity	Not more than 0.10%.	Max.: 0.02%
Limit of late eluting impurities:		
Gabapentin related compound D	Not more than 0.10%.	<0.01%
Individual unknown impurity	Not more than 0.10%.	Max.: 0.01%
Total impurities:	Not more than 0.3%.	0.04%
Assay (HPLC)	Between 98.0% and 102.0% (anhydrous basis).	100.6%

0.01%: Disregard limit for Impurity A, E, D and unknown impurities
0.02%: DL for Impurity B 0.05%: QL for Impurity B

NOTE: The product meets the requirements of the current USP monograph for Gabapentin.

Q. Laboratory Manager	**Quality Director**
APPROVED	APPROVED
E. LÓPEZ	P. VERGE
22/03/2022	22/03/2022