MENADIONA
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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:	3099/91357		
Date of Manufacture:	JUL-2019	**Retest Date:**	JUN-2024

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%.	0.05%
pH	Between 6.5 and 8.0, in a solution (1 in 50).	7.2
Water (KF)	Not more than 0.5%.	0.03%
Sulphated ash	Not more than 0.1%.	0.07%
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%.	nd
Gabapentin related compound A	Not more than 0.05%.	0.00%
Gabapentin related compound B	Not more than 0.06%.	nd
Individual unknown impurity	Not more than 0.10%.	Max.: 0.05%
Limit of late eluting impurities:		
Gabapentin related compound D	Not more than 0.10%.	nd
Individual unknown impurity	Not more than 0.10%.	Max.: 0.00%
Total impurities:	Not more than 0.3%.	0.11%
Assay (HPLC)	Between 98.0% and 102.0% (anhydrous basis).	98.3%

nd: Not detected.

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

Q. Laboratory Manager	**Quality Director**
APPROVED	APPROVED
C. DE TORO 02/08/19	P. VERGE 02/08/19