



08/07/2022

METAPHARMACEUTICAL

N DE LOTE:

0120922

MENADIONA

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CERTIFICATE OF ANALYSIS

CA.EP.3099/005/21


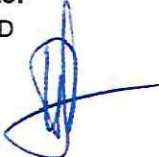
Product name:	GABAPENTIN	CAS Number:	[60142-96-3]
Chemical name:	1-(Aminomethyl)cyclohexaneacetic acid		
Molec.Formula:	C ₉ H ₁₇ NO ₂	Molec.Weight:	171.24
Batch N°:	3099/21451	Delivered qty.:	--
Date of Manufacture:	JUN-2022	Retest Date:	MAY-2027

TESTS	SPECIFICATIONS	RESULTS
Appearance	White or almost white, crystalline powder.	Complies
Solubility	Sparingly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride.	Complies
Identification		
Infrared Absorption	Matches with the <i>Gabapentin CRS</i> .	Complies
Appearance of solution		
Degree of opalescence	Not more than reference suspension I.	Complies
Degree of coloration	Not more than reference solution B ₉ .	Complies
pH	6.5 to 7.5	7.0
Chlorides	Not more than 100 ppm	<20 ppm
Water	Not more than 0.3%	0.04%
Sulphated ash	Not more than 0.1%	0.00%
Loss on drying	Not more than 0.5%	0.19%
Particle size	More than 90% passes through 400µm	Complies
Related substances		
Test A (HPLC)		
Impurity A	Not more than 0.05%	<0.05%
Individual unspecified impurity	Not more than 0.10%	0.10%
Related substances		
Test B (HPLC)		
Individual unspecified impurity	Not more than 0.05%	<0.03%
Total impurities (Test A+ Test B)	Not more than 0.3%	0.10%
Assay (HPLC)	Between 98.0% and 102.0% (anhydrous substance).	99.2%

nd: Not detected
20 ppm: DL for chlorides

0.05%: DL for related substances Test A
0.03%: DL for related substances Test B

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

Quality Assurance APPROVED  J. JUNCA 08/07/2022	Quality Director APPROVED  P. VERGE 08/07/2022
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