



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 213337

Product:	GABAPENTIN
Lot:	213337
Expiry date:	01/04/2025
Reference:	Cumple PhEur10.4
Synonyms:	
Formula:	C9H17NO2
Molecular weight:	171,24 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	=
pH aqueous solution 2%	7,3	6,5 - 7,5	=
Water	0,01 %	<= 0,3%	
Heavy metals	<= 20 ppm	<= 20 ppm	#
Related substances (HPLC)	Conform	Test PhEur	=
Sulphated ashes	0,00 %	<= 0,1%	=
Chlorides	<= 100 ppm	<= 100 ppm	=
Assay (HPLC)	99,3 %	97,5-102,0%	
Impurity A	NDT	<= 0,15 %	=
Unspecified impurities (test A)	NDT	<= 0,10 %	=
Unspecified impurities (test B)	NDT	<= 0,05 %	=
Total impurities (sum test A + B)	NDT	<= 0,5 %	=
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. sparingly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride. It dissolves in dil. aci. and dil solutions of alkali hydrox.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 13/07/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00406

Manufacturer batch: B210001

Product	Name	Capacity	Batch
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1115246	GABAPENTINA	10 g	213337-F-1
1115248	GABAPENTINA	50 g	213337-I-1
1115248	GABAPENTINA	50 g	213337-I-2
1115250	GABAPENTINA	250 g	213337-N-1
1115250	GABAPENTINA	250 g	213337-N-2
1115252	GABAPENTINA	1 kg	213337-P-2
1115252	GABAPENTINA	1 kg	213337-P-3
1115252	GABAPENTINA	1 kg	213337-P-4
1370173	GABAPENTINA (FLB)	1 kg	213337-P-1
1370173	GABAPENTINA (FLB)	1 kg	213337-P-5

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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