



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240976

Product:	GABAPENTIN
Lot:	240976
Expiry date:	28/02/2027
Reference:	Cumple PhEur11.4
Synonyms:	
Formula:	C9H17NO2
Molecular weight:	171,24 g/mol

Assay	Result	Specification	
Unspecified impurities (test A)	< 0,05 %	<= 0,10 %	
Unspecified impurities (test B)	0,03 %	<= 0,05 %	
Impurity A	0,01 %	<= 0,15 %	
Appearance of solution	Conform	Test PhEur	
Nitrosamine impurities	Conform	Test PhEur	#
pH	7,1	6,5 - 7,5	
Identification	Conform	Test PhEur	
Total impurities (sum test A + B)	0,04 %	<= 0,5 %	
Organoleptic properties	Conform	PhEur	
Residual solvent: Ethanol	< 5000 ppm	<=5000 ppm	#
Related substances (HPLC)	Conform	Test PhEur	
Sulphated ashes	0,01 %	<= 0,1%	
Water	0,02 %	<= 0,3%	
Elemental impurities	Conform	Test PhEur	#
Chlorides	20 ppm	<= 100 ppm	
Assay (HPLC)	100,2 %	97,5-102,0%	

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: 30/05/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00446 ZHEJIANG CHIRAL MEDICINE CHEMICALS, Co., Ltd.

Manufacturer batch: GAA-2403009

Product	Name	Capacity	Batch
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1115248	GABAPENTINA	50 g	240976-I-1
1115250	GABAPENTINA	250 g	240976-N-1
1115252	GABAPENTINA	1 kg	240976-P-1
1115253	GABAPENTINA	5 kg	240976-Q-1

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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