



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240611

Product:	GABAPENTIN
Lot:	240611
Expiry date:	30/10/2026
Reference:	Cumple PhEur11.4
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	7,0	6,5 - 7,5	
Water	0,02 %	<= 0,3%	
Elemental impurities	Conform	Test PhEur	#
Related substances (HPLC)	Conform	Test PhEur	
Sulphated ashes	0,02 %	<= 0,1%	
Chlorides	10 ppm	<= 100 ppm	
Assay (HPLC)	99,8 %	97,5-102,0%	
Impurity A	0,01 %	<= 0,15 %	
Unspecified impurities (test A)	< 0,05 %	<= 0,10 %	
Unspecified impurities (test B)	< 0,03 %	<= 0,05 %	
Total impurities (sum test A + B)	< 0,5 %	<= 0,5 %	
Residual solvent: Ethanol	< 5000 ppm	<=5000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

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: 02/04/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

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

Manufacturer batch: GAA-2311014

Product	Name	Capacity	Batch
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1115246	GABAPENTINA	10 g	240611-F-1
1115248	GABAPENTINA	50 g	240611-I-2
1115250	GABAPENTINA	250 g	240611-N-1
1115252	GABAPENTINA	1 kg	240611-P-2
1115253	GABAPENTINA	5 kg	240611-Q-2
1370173	GABAPENTINA (FLB)	1 kg	240611-P-1
1370216	GABAPENTINA (FLB)	5 kg	240611-Q-1
1370240	GABAPENTINA (FLB)	50 g	240611-I-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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