



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 222320**

Product:	GABAPENTIN
Lot:	222320
Expiry date:	31/01/2026
Reference:	Cumple PhEur10.7
Synonyms:	
Formula:	C9H17NO2
Molecular weight:	171,24 g/mol

Assay	Result	Specification	
Unspecified impurities (test B)	<= 0,03 %	<= 0,05 %	
Identification	Conform	Test PhEur	
Total impurities (sum test A + B)	<= 0,05 %	<= 0,5 %	
Impurity A	<= 0,05 %	<= 0,15 %	
Unspecified impurities (test A)	<= 0,05 %	<= 0,10 %	
pH	7,4	6,5 - 7,5	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Water	0,11 %	<= 0,3%	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Organoleptic properties	Conform	PhEur	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Appearance of solution	Conform	Test PhEur	
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Sulphated ashes	0,01 %	<= 0,1%	
Chlorides	0 ppm	<= 100 ppm	
Elemental impurities	Conform	Test PhEur	#
Related substances (HPLC)	Conform	Test PhEur	
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: 04/05/2022

Judgement:  
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00430 HIKAL Ltd.

Manufacturer batch: B71010622-043

Product	Name	Capacity	Batch
1115246	GABAPENTINA	10 g	222320-F-1
1115248	GABAPENTINA	50 g	222320-I-1
1115250	GABAPENTINA	250 g	222320-N-1
1115252	GABAPENTINA	1 kg	222320-P-2
1115252	GABAPENTINA	1 kg	222320-P-3
1370173	GABAPENTINA (FLB)	1 kg	222320-P-1
1370216	GABAPENTINA (FLB)	5 kg	222320-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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