

Certificate of Analysis

Product name: **Gabapentinum**

Batch number / Weight: **23F09-B03-229813 / 250 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23F09-B03 / INS-23-5545**

Reference Code / No.: **V02269 / G71010622/624**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
pH	6,5 - 7,5	7,30		
Related substances	Conform	Conform		
Impurity A	<=0,5	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Related substances (B)	Conform	Conform		
Unspecified impurities	<=0,05	<0,03	%	
Total impurities (A and B)	<=0,5	0,00	%	
Chlorides	<=100	2,4	ppm	
Water	<=0,3	0,02	%	
Sulfated ash	<=0,1	0,02	%	
Assay	97,5 - 102,0	100,67	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents acc CEP				
Methanol	<=250	40,7	ppm	
Acetone	<=100	<LOD: 1,13	ppm	
Isopropanol	<=1000	101,0	ppm	
Toluene	<=100	<LOD: 0,45	ppm	
Total aerobic microbial count (TA)	<=10 ³	<10	CFU/g	
Total yeasts and moulds (TYMC)	<=10 ²	<10	CFU/g	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, Quercus, CBMiA

Release:
Dominika Soltysik
Qualified Person

13-09-2023

Expiration: 30-11-2026

Conclusion: APPROVED

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