

Certificate of Analysis

Product name: **Carbamazepinum**

Batch number / Weight: **23J02-B04-232282 / 50 G**

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

Number of analysis / Inspection Code **23J02-B04 / INS-23-8243**

Reference Code / No.: **V00375 / 101042328**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	189 - 193	192,1	°C	
Identification B	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,15	<0,05	%	
Impurity E	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Chlorides	<=140	<140	ppm	
Loss on drying	<=0,5	0,09	%	
Sulphated ash	<=0,1	0,02	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,0 - 102,0	99,55	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer

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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, EI Spol

Release:

Ewelina Gadzinowska

Qualified Person

14-12-2023

Expiration: 30-04-2026

Conclusion: APPROVED

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