Certificate of Analysis

Product name: **Piracetamum**

Batch number / Weight: **23D17-B02-234243 / 250 G**

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

Number of analysis / Inspection Code **23D17-B02 / INS-23-3721**

Reference Code / No.: **V01863 / DY0302300236**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Related substances	Conform	Conform		
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=0,3	0,00	%	
Loss on drying	<=1,0	0,18	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Piracetam	98,0 - 102,0	100,38	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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 lab

Release:
Dominika Sołtysik
Qualified Person

21-11-2023

Expiration: 14-02-2028

Conclusion: APPROVED

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