

Certificate of Analysis

Product name: Melatoninum

Batch number / Weight: 22I16-B05-233025 / 1 G

Analysed according to: British Pharmacopoeia

Number of analysis / Inspection Code 22I16-B05 / INS-22-7913

Reference Code / No.: V01741 / 20220508

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to slightly beige powder	Conform		
Identification	Conform	Conform		
Related substances	Conform	Conform		
5-Methoxytryptamine	$\leq 0,1$	$< 0,05$	%	
Any secondary peak	$\leq 0,1$	$< 0,05$	%	
Sum secondary peaks	≤ 1	0,00	%	
Water	$\leq 0,3$	0,12	%	
Sulphated ash	$\leq 0,1$	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Melatonin	98,0 - 102,0	99,65	%m/m	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
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:
Agnieszka Pszczółka
Qualified Person

14-09-2023

Expiration: 14-05-2025

Conclusion: APPROVED

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