

## Certificate of Analysis

**Product name:** Melatoninum  
**Batch number / Weight:** 22I16-B05-235227 / 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	$\leq 1$	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:  
 Ewelina Gadzinowska  
 Qualified Person

15-12-2023

Expiration: 14-05-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl      Fagron Services Northern Europe Sp. z o.o.  
 ul. Armii Krajowej 3  
 32-540 Trzebinia, Poland  
 e-mail: fsne@fagron.pl

fagron.pl      Fagron sp. z o.o.  
 ul. Pasternik 26, 31-354 Kraków, Poland  
 tel.: +48 12 3343 512  
 e-mail: biuro@fagron.pl