

Certificate of Analysis

Product name: Melatoninum

Batch number / Weight: 22A12-B09-218664 / 5 G

Analysed according to: British Pharmacopoeia

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to slightly beige powder	Conform		
Identification	Conform	Conform		
Related substances	Conform	Conform		
5-Methoxytryptamine	<=0,5	<0,05	%	
Any secondary peak	<=0,1	<0,05	%	
Sum secondary peaks	<=1	0,00	%	
Water	<=0,3	0,10	%	
Sulphated ash	<= 0,1	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Melatonin	98,0 - 102,0	101,61	%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

Analysis performed by the authorized lab.

Release:

Dominika Sołtysik Qualified Person

25-04-2022

Expiration: 14-11-2024

Conclusion: APPROVED

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