

Certificate of Analysis

Productname: Melatoninum
Number of analysis/Inspection Code: 1 / KEUR-180718B
Batchnumber: 20A15-F03-367973
Reference code / No.: 3848 / MLT/519021
Analysed according to: BP2019

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification	Conform	Conform		IR-spectrum
Related substances	Conform	Conform		HPLC
5-Methoxytryptamine	<=0,5	<0,01	%	
Any secondary peak	<=0,1	<0,05	%	
Total impurities	<=1,0	<0,05	%	
Water	<=0,3	0,0	%	Karl Fischer
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Melatonin	98,0 - 102,0	100,8	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/25/20

Expiration: 05-2024

Conclusion: APPROVED

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