

CERTIFICATE OF ANALYSIS

MELATONIN F N-(2-(5-methoxy-1H-indol-3-yl)ethyl)acetamide

BATCH:	0024001502	QUANTITY:	10 KG
MANUFACTURING SITE:	CHIGNOLO D'ISOLA		
MANUFACTURING DATE:	05/03/2024	RETEST DATE:	04/07/2029
CODE MATERIAL:	FC00000019	REF.:	BP/EP
ANALYSIS REF. NO.:	890000014077	SPEC.REV.:	28
CAS NO. :	73-31-4		

TESTS	SPECIFICATIONS	UM	RESULTS	ANALYTICAL METHOD REFERENCES
Aspect	Crystalline powder		Crystalline Powder	
Colour	White to slightly yellowish		White	
Identification (IR)	Must comply		Complies	EP 2.2.24
Identification (HPLC)	Must comply		Complies	
Solubility (5% w/v ethyl alcohol)	Complete		Complete	
Appearance of solution	Clear, <BY3 EP		Clear, <BY3 EP	PHEUR. <2.2.1>
Melting Point	116.0 - 118.5	°C	117.3	PHEUR. 2.2.14
Water Content	<= 0.3	%	0.1	EP 2.5.12
Assay (HPLC)	98.0 - 102.0	% d.b.	100.2	
Purity (HPLC)	>= 99.5	%	100.0	
Each Unknown Impurity (HPLC)	<= 0.10	%	< 0.05	
5-Methoxytryptamine (HPLC)	<= 0.10	%	< 0.01	
Total Impurities (HPLC)	<= 0.5	%	0.0	
Sulphated Ash	<= 0.1	%	0.0	PHEUR. 2.4.14
Residual Methyl Alcohol	<= 1 000	ppm	< 15	
Residual 2-Propanol	<= 2 000	ppm	306	
Residual Tert Butyl Methylether	<= 1 000	ppm	< 16	
Ethyl Acetate (GC)	<= 1 000	ppm	< 51	

Electronically signed by:

Chiara Galimberti
Quality Control
06/21/2024 - APPROVED

Andrea Doria
Qualified Person
06/24/2024 - RELEASED

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