

CERTIFICATE OF ANALYSIS

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

BATCH:	0023001766	QUANTITY:	10 KG
MANUFACTURING SITE:	CHIGNOLO D'ISOLA	RETEST DATE:	04/30/2028
MANUFACTURING DATE:	05/27/2023	REF.:	BP/EP
CODE MATERIAL:	FC00000019	SPEC.REV.:	26
ANALYSIS REF. NO.:	040000018162		
CAS NO. :	73-31-4		

<u>TESTS</u>	<u>SPECIFICATIONS</u>	<u>UM</u>	<u>RESULTS</u>	<u>ANALYTICAL METHOD</u> <u>REFERENCES</u>
Aspect	Crystalline powder		Crystalline Powder	
Colour	White to slightly yellowish		Slightly yellowish	
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	118.0	PHEUR. 2.2.14
Water Content	<= 0.3	%	0.1	EP 2.5.12
Assay (HPLC)	98.0 - 102.0	% d.b.	100.4	
Purity (HPLC)	>= 99.5	%	100.0	
Each Unknown Impurity (HPLC)	<= 0.10	%	< 0.05	
5-Methoxytryptamine (HPLC)	<= 0.10	%	0.00	
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	352	
Residual Tert Butyl Methylether	<= 1 000	ppm	< 16	
Ethyl Acetate (GC)	<= 1 000	ppm	< 51	

Electronically signed by:

Stefano Gobbato
Quality Control
07/10/2023 - APPROVED

Sergio Fracchia
Qualified Person
07/11/2023 - RELEASED

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