

CERTIFICATE OF ANALYSIS

MELATONIN F

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

BATCH:	0022000282	QUANTITY:	10 KG
MANUFACTURING SITE:	CHIGNOLO D'ISOLA		
MANUFACTURING DATE:	02/18/2022	RETEST DATE:	01/23/2027
CODE MATERIAL:	FC00000019	REF.:	BP
ANALYSIS REF. NO.:	040000014612	SPEC.REV.:	23
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	Ivory to beige		Ivory	
Identification (IR)	Must comply		Complies	
Identification (HPLC)	Must comply		Complies	
Solubility (5% w/v ethyl alcohol)	Complete		Complete	
Appearance of solution	Clear, <BY3 EP		Clear, <BY3 EP	Ph.Eur. <2.2.1>
Melting Point	116.0 - 118.5	°C	117.2	
Water Content	<= 0.3	%	0.0	
Assay (HPLC)	98.0 - 102.0	% d.b.	99.9	
Purity (HPLC)	>= 99.0	%	100.0	
Each Unknown Impurity (HPLC)	<= 0.10	%	< 0.05	
5-Methoxytryptamine (HPLC)	<= 0.10	%	< 0.05	
Total Impurities (HPLC)	<= 0.5	%	0.0	
Sulphated Ash	<= 0.1	%	0.0	
Residual Methyl Alcohol	<= 1 000	ppm	< 15	
Residual 2-Propanol	<= 2 000	ppm	464	
Residual Tert Butyl Methylether	<= 1 000	ppm	< 52	
Ethyl Acetate (GC)	<= 1 000	ppm	61	

Electronically signed by:

Stefano Gobbato
Quality Control
03/03/2022 - APPROVED

Sergio Fracchia
Qualified Person
03/09/2022 - RELEASED

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