

CERTIFICATE OF ANALYSIS

MELATONIN F

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

BATCH:	Z020004010	QUANTITY:	10 KG
MANUFACTURING SITE:			
MANUFACTURING DATE:	11/26/2020	RETEST DATE:	10/31/2025
CODE MATERIAL:	FC00000019	REF.:	BP
ANALYSIS REF. NO.:	080000003165	SPEC.REV.:	20
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	118.5	
Water Content	<= 0.3	%	0.0	
Assay (HPLC)	98.0 - 102.0	% d.b.	100.1	
Purity (HPLC)	>= 99.0	%	100.0	
Each Unknown Impurity (HPLC)	<= 0.10	%	< 0.05	
5-Methoxytryptamine (HPLC)	<= 0.10	%	< 0.05	
Total Impurities (HPLC)	<= 1.0	%	0.0	
Sulphated Ash	<= 0.1	%	< 0.0	
Residual Methyl Alcohol	<= 1 000	ppm	< 15	
Residual 2-Propanol	<= 2 000	ppm	406	
Residual Tert Butyl Methylether	<= 1 000	ppm	< 16	
Ethyl Acetate (GC)	<= 1 000	ppm	53	

NOTE:

Test n° 511-693: Disregard Limit=0,05%

Electronically signed by:

Giulio Lorenzi
Controllo Qualità
03/08/2021 - APPROVED

Sergio Fracchia
Qualified Person
03/08/2021 - RELEASED

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