

MANUFACTURING SITE Via Bedeschi, 22 - 24040 CHIGNOLO D'ISOLA (BG) - Italy



Via Bedeschi 22 - 24040 Chignolo d'Isola - BG - Italy - Tel +39 0354991811 - Fax +39 0354991812 - info@flamma.it - www.flamma.it

CERTIFICATE OF ANALYSIS

MELATONIN F

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

BATCH	170014	CODE	FC00000019
QUANTITY	KG - 230,99	SPEC. CODE	FC00000019
MANUFACTURING DATE	23/11/2017	REV.	14
RETEST DATE	28/10/2022	REFERENCE	BP
ANALYSIS DATE	22/12/2017	ANALYTICAL REPORT NR.	2017003124

TESTS	LIMITS			RESULTS
	M.U.	MIN	MAX	
ASPECT			CRYSTALLINE POWDER	CRYSTALLINE POWDER
COLOUR			IVORY TO BEIGE	COMPLIES
IDENTIFICATION (IR)			MUST COMPLY	COMPLIES
IDENTIFICATION (HPLC)			MUST COMPLY	COMPLIES
SOLUBILITY (5% w/v ethyl alcohol)			COMPLETE	COMPLIES
CLARITY, COLOUR SOLUTION			CLEAR, <Y4 EP	CLEAR, <Y4 EP
MELTING POINT	°C	116.0	118.5	117.4
WATER CONTENT	%		0.3	0.0
ASSAY (HPLC)	% d.b.	98.0	102.0	99.6
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
HEAVY METALS	ppm		10	< 10
SULPHATED ASH	%		0.1	0.1
RESIDUAL METHYL ALCOHOL	ppm		1000	0
RESIDUAL 2-PROPANOL	ppm		2000	467
RESIDUAL TERT BUTYL METHYLETHYL	ppm		1000	7
ETHYL ACETATE (GC)	ppm		1000	74

NOTES: Colour: Ivory 23/11/17 FB
Test Purity, each unknown impurity, 5-Methoxytryptamine and total impurities: disregard limit: 0.05% 28/11/2017 MK

APPROVED

QUALITY CONTROL
Dr. Stefano Gobbato

NOTE: This certificate of analysis has been generated electronically and it is valid without a signature
Unique identification is assigned by batch number + compound code