

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	160007	CODE	FC00000019
QUANTITY	KG - 185,89	SPEC. CODE	FC00000019
MANUFACTURING DATE	13/10/2016	REV.	12
RETEST DATE	17/09/2021	REFERENCE	BP
ANALYSIS DATE	07/11/2016	ANALYTICAL REPORT NR.	2016002913

TESTS	LIMITS			RESULTS
	M.U.	MIN	MAX	
ASPECT				CRYSTALLINE POWDER
COLOUR				CRYSTALLINE POWDER
IDENTIFICATION (IR)				IVORY TO BEIGE
IDENTIFICATION (HPLC)				MUST COMPLY
SOLUBILITY (5% w/v ethyl alcohol)				MUST COMPLY
CLARITY, COLOUR SOLUTION				COMPLETE
MELTING POINT	°C	116.0	118.5	CLEAR, <Y4 EP
WATER CONTENT	%		0.3	117.6
ASSAY (HPLC)	% d.b.	98.0	102.0	0.1
PURITY (HPLC)	%	99.0		99.3
EACH UNKNOWN IMPURITY (HPLC)	%		0.10	100.0
5-METHOXYTRYPTAMINE (HPLC)	%		0.10	< 0.05
TOTAL IMPURITIES (HPLC)	%		1.0	< 0.05
HEAVY METALS	ppm		10	0.0
SULPHATED ASH	%		0.1	< 10
RESIDUAL METHYL ALCOHOL	ppm		1000	0.0
RESIDUAL 2-PROPANOL	ppm		2000	6
RESIDUAL TERT BUTYL METHYLETHYL	ppm		1000	397
ETHYL ACETATE (GC)	ppm		1000	4
				56

NOTES: Colour: beige
FB 26/10/2016

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