

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



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CERTIFICATE OF ANALYSIS

MELATONIN F

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

BATCH	160006	CODE	FC00000019
QUANTITY	KG - 219,94	SPEC. CODE	FC00000019
MANUFACTURING DATE	05/05/2016	REV.	11
RETEST DATE	09/04/2021	REFERENCE	BP
ANALYSIS DATE	31/05/2016	ANALYTICAL REPORT NR.	2016001375

TESTS	LIMITS			RESULTS
	M.U.	MIN	MAX	
ASPECT			CRYSTALLINE POWDER	COMPLIES
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	COMPLIES
MELTING POINT	°C	116.0	118.5	118.1
WATER CONTENT	%		0.3	0.0
ASSAY (HPLC)	% d.b.	98.0	102.0	99.4
PURITY (HPLC)	%	99.0		0100.0
EACH UNKNOWN IMPURITY (HPLC)	%		0.10	< 0.05
5-METHOXYTRIPRAMINE (HPLC)	%		0.15	< 0.05
TOTAL IMPURITIES (HPLC)	%		1.0	0.0
HEAVY METALS	ppm		10	< 10
SULPHATED ASH	%		0.1	0.0
RESIDUAL METHYL ALCOHOL	ppm		1000	0
RESIDUAL 2-PROPANOL	ppm		2000	475
RESIDUAL TERT BUTYL METHYLETHYL	ppm		1000	10
ETHYL ACETATE (GC)	ppm		1000	85

NOTES: Aspect: Crystalline Powder, Colour: Ivory 05/05/16 EG

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