



CERTIFICATE OF ANALYSIS

MELATONIN F

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

BATCH	150011	CODE	FC00000019
QUANTITY	KG - 197,39	SPEC. CODE	FC00000019
MANUFACTURING DATE	14/11/2015	REV.	10
RETEST DATE	18/10/2020	REFERENCE	BP
ANALYSIS DATE	09/12/2015	ANALYTICAL REPORT NR.	2015002931

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	118.2
WATER CONTENT	%		0.3	0.0
ASSAY (HPLC)	% d.b.	98.0	102.0	99.2
PURITY (HPLC)	%	99.0		100.0
EACH UNKNOWN IMPURITY (HPLC)	%		0.10	< 0.05
5-METHOXYTRYPTAMINE (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	8
RESIDUAL 2-PROPANOL	ppm		2000	339
RESIDUAL TERT BUTYL METHYLETHYL	ppm		1000	3
ETHYL ACETATE (GC)	ppm		1000	33

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