



CERTIFICATE OF ANALYSIS

MELATONIN F

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

BATCH	150012	CODE	FC00000019
QUANTITY	KG - 220,04	SPEC. CODE	FC00000019
MANUFACTURING DATE	18/11/2015	REV.	10
RETEST DATE	22/10/2020	REFERENCE	BP
ANALYSIS DATE	09/12/2015	ANALYTICAL REPORT NR.	2015002948

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	99.8
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	0
RESIDUAL 2-PROPANOL	ppm		2000	372
RESIDUAL TERT BUTYL METHYLETHYL	ppm		1000	7
ETHYL ACETATE (GC)	ppm		1000	22

APPROVED

QUALITY CONTROL
Dr. Stefano GobbatoNOTE: This certificate of analysis has been generated electronically and it is valid without a signature
Unique identification is assigned by batch number + compound code