

CERTIFICATE OF ANALYSIS

MELATONIN F

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

BATCH	120006	CODE	FC00000019
QUANTITY	KG - 220	REFERENCE	BP
MANUFACTURING DATE	20/06/2012	ANALYTICAL REPORT NR.	2012001667
RETEST DATE	25/05/2017	ANALYSIS DATE	10/07/2012

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	118.3
WATER CONTENT	%		0.3	0.1
ASSAY (HPLC)	% d.b.	98.0	102.0	99.9
PURITY (HPLC)	%	99.0		99.9
EACH UNKNOWN IMPURITY (HPLC)	%		0.10	0.00
5-METHOXYTRYPTAMINE (HPLC)	%		0.15	0.05
TOTAL IMPURITIES (HPLC)	%		1.0	0.1
HEAVY METALS	ppm		10	< 10
SULPHATED ASH	%		0.1	0.1
RESIDUAL METHYL ALCOHOL	ppm		1000	17
RESIDUAL 2-PROPANOL	ppm		2000	440
RESIDUAL TERT BUTYL METHYLETHYL	ppm		1000	15
ETHYL ACETATE (GC)	ppm		1000	54

NOTES: Extra Test: Arsenic <1ppm; Cadmium <1ppm; Mercury <1ppm; Lead <1ppm; Heavy Metals <10ppm
29/06/12 CF

APPROVED

QUALITY CONTROL
Dr. Stefano Gobbato

NOTE: This certificate of analysis has been generated electronically and it is valid without a signature