

Date 05/05/18




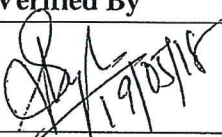
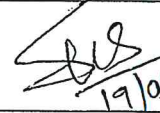
SWATI SPENTOSE PVT. LTD. UNIT-I

Mfg. Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India. Ph.: 0260-2433133, 2401533

CERTIFICATE OF ANALYSIS

Product Name	Melatonin (BP)	Page No.: 1 of 2
Batch No.	MLT/118002	A. R. No.
Batch size	41.50 Kg	Released on
Manufacturing Date	May-2018	Retest Date
		Apr-2022

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Appearance	A white to off white crystalline powder.	Off white crystalline powder.
2.	Solubility	Slightly soluble in Water; soluble in Acetone, Ethyl acetate and Methanol.	Complies
3.	Melting Point	It melts at about 117°C	117.6°C
4.	Identification	A. Infrared Absorption spectrum: The infrared absorption spectrum should be concordant with the References standard / Working standard of Melatonin.	Complies
5.	Related substances (By HPLC)	5-methoxytryptamine Impurity: NMT 0.5%	Not Detected
		Any other secondary impurity: NMT 0.1%	0.03%
		Sum of impurities: NMT 1.0%	0.09%
6.	Water Content	Not more than 0.3%	0.13%
7.	Sulphated Ash	Not more than 0.1%	0.04%
8.	Assay (By HPLC)	Not less than 98.0% and not more than 102% (calculated on anhydrous basis)	99.7%

Activity	Prepared By	Verified By	Approved By
Sign & Date	 19/05/18	 19/05/18	 19/05/18
Name	Mr. Jigar Patel	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	Executive-QA	Manager-QC	Corporate Head-QA & QC



SWATI SPENTOSE PVT. LTD. UNIT-I

Mfg. Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India. Ph.: 0260-2433133, 2401533

CERTIFICATE OF ANALYSIS

Product Name	Melatonin (BP)	Page No.: 2 of 2
Batch No.	MLT/118002	A. R. No.
Batch size	41.50 Kg	Released on
Manufacturing Date	May-2018	Retest Date


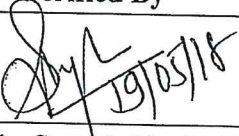

Sr. No.	TEST	SPECIFICATION	RESULTS
9.	Residual solvents (By GC)	Ethanol: Not more than 5000 ppm	Not Detected
		Methylene Dichloride: Not more than 600 ppm	Not Detected
		Ethyl acetate: Not more than 5000 ppm	458 ppm
		Pyridine: Not more than 200 ppm	Not Detected

CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per **BP-2018** Specification.

STORAGE CONDITION:

Protected from light and stored at a temperature not exceeding 30°C.

Activity	Prepared By	Verified By	Approved By
Sign & Date	 19/05/18	 19/05/18	 19/05/18
Name	Mr. Jigar Patel	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	Executive-QA	Manager-QC	Corporate Head-QA & QC