

SWATI SPENTOSE PVT. LTD. UNIT-I

Mfg. Site Address: A-1/2162 & 2103, Phase-II, G.I.D.C., Vapi-396195, Gujarat, India. Ph.: 0260-2433133, 2401533

CERTIFICATE OF ANALYSIS

Product Name	Melatonin (BP)	Page No.:	1 of 2
Batch No.	MLTA17001	A. R. No.	FP/17/089
Batch size	89.66 Kg	Released on	13/04/2017
Manufacturing Date	Apr-2017	Retest Date	Mar-2020

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	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	116°C
4.	Identification	A. Infrared Absorption spectrum: The infrared absorption spectrum should be concordant with the references spectrum of melatonin.	Complies
5.	Related substances (By HPLC)	3-methoxytryptamine impurity: NMT 0.5%	Not detected
		Any other secondary impurity: NMT 0.1%	0.02%
		Sum of impurities: NMT 1.0%	0.05%
6.	Heavy Metals	Not more than 20 ppm	Less than 20 ppm
7.	Water Content	Not more than 0.3%	0.25%
8.	Sulphated Ash	Not more than 0.1%	0.04%
9.	Assay (By HPLC)	Not less than 98.0% and not more than 102% (calculated on anhydrous basis)	99.9%

Activity	Prepared By	Verified By	Approved By
Sign & Date	 13/04/17	 13/04/17	 13/04/17
Name	P. Agar Pal	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-17197 & 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.	ML7Y117001	A. R. No.
Batch size	89.66 Kg	Released on
Manufacturing Date	Apr-2017	Re-test Date
		Mar-2020

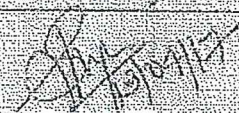
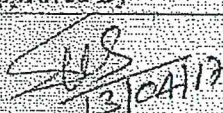
Sr. No.	TEST	SPECIFICATION	RESULTS
		Pyridine: Not more than 200 ppm	30 ppm
		Methylene Dichloride: Not more than 600 ppm	7 ppm
		Ethanol: Not more than 5000 ppm	Not Detected
		Ethyl acetate: Not more than 5000 ppm	231 ppm

CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per BP-2016 as per customer specification.

STORAGE CONDITION:

Protect from light and moisture at a temperature not exceeding 30°C.

Activity	Prepared By	Verified By	Approved By
Sign & Date	 13/04/17	 13/04/17	 13/04/17
Name	Mr. Jigar Patel	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	Executive-QA	Manager-QC	Corporate Head-QA & QC