



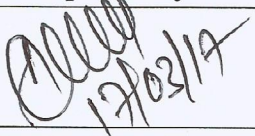
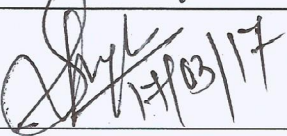
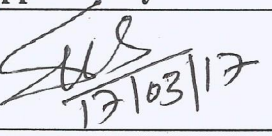
SWATI SPENTOSE PVT. LTD. UNIT-I

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/116003	A. R. No.	FP/16/236
Batch size	92.00 Kg	Released on	04/10/2016
Manufacturing Date	Sep-2016	Retest Date	Aug-2018

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	119.6 °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)	5-methoxytryptamine Impurity: NMT 0.5%	Not detected
		Any other secondary impurity: NMT 0.1%	0.01%
		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%	0.03%
8.	Sulphated Ash	Not more than 0.1%	0.03%
9.	Assay (By HPLC)	Not less than 98.0% and not more than 102% (calculated on anhydrous basis)	99.87%

Activity	Prepared By	Verified By	Approved By
Sign & Date	 17/03/17	 17/03/17	 17/03/17
Name	Mr. Amit Dwivedi	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	officer-QA	Manager-QC	Corporate Head-QA & QC



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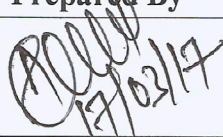
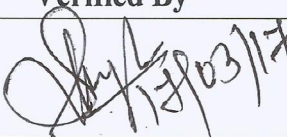
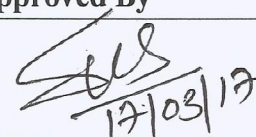
Sr. No.	TEST	SPECIFICATION	RESULTS
10.	Residual solvents (By GC)	Pyridine: Not more than 200 ppm	24 ppm
		Methylene Dichloride: Not more than 600 ppm	41 ppm
		Ethanol: Not more than 5000 ppm	Not Detected
		Ethyl acetate: Not more than 5000 ppm	620 ppm

CONCLUSION:

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

STORAGE CONDITION:

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

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Sign & Date	 17/02/17	 17/03/17	 17/03/17
Name	Mr. Amit Dwivedi	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	officer-QA	Manager-QC	Corporate Head-QA & QC