



# SWATI SPENTOSE PVT. LTD. UNIT-I

Manufacturing Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India

## QUALITY ASSURANCE DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name	Melatonin (BP)	Page No. 1 of 1
Batch No	MLT/116002	A.R. No
Batch Size	49.00 kg	Released on
Manufacturing Date	April-2016	Retest Date

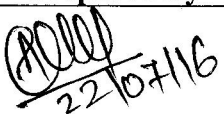
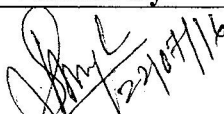
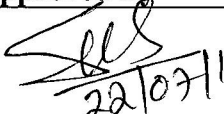
Tests	Specification	Results
Description	A white to off white crystalline powder.	Off white crystalline powder.
Solubility	Slightly soluble in water soluble in acetone, ethyl acetate and methanol.	Complies
Melting Point	About 117°C	116°C
Identification	A. Infrared Absorption spectrum: The infrared absorption spectrum should be concordant with the references spectrum of melatonin.	Complies
Related Substances (By HPLC)	5-methoxytryptamine Impurity: Not more than 0.5% Any other secondary impurity: Not more than 0.1% Sum of impurities: Not more than 1%	Not detected 0.03% 0.06%
Heavy Metals	Not more than 20 ppm	Less than 20 ppm
Water Content	Not more than 0.3%	0.14%
Sulphated Ash	Not more than 0.1%	0.03%
Assay (By HPLC)	Not less than 98.0% and not more than 102% (calculated on anhydrous basis)	99.41%
Residual Solvent (By GC)	Pyridine: Not more than 200 ppm Methylene Dichloride: Not more than 600 ppm Ethanol: Not more than 5000 ppm Ethyl acetate: Not more than 5000 ppm	Not detected 68 ppm Not detected 341 ppm

### CONCLUSION:

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

### STORAGE CONDITION:

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

	Prepared By	Verified By	Approved By
Sign & Date	 22/07/16	 22/07/16	 22/07/16
Name	Mr. Amit Dwivedi	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	officer-QA	Manager-QC	Corporate Head-QA & QC