

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/117001	T/117001 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	Description A white to 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	
	Related substances (By HPLC)	5-methoxytryptamine Impurity: NMT 0.5%	Not detected	
5.		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	ntent 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	fee Job 13/04/17	104/3/04/14	JUS 117	
Name	Mr. Jigar Patel	Mr. Suresh Singh	Mr. S. K. Srivastava	
Designation Executive-QA		Manager-QC	Corporate Head-QA & QC	



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	The state of the s	Pyridine: Not more than 200 ppm	30 ppm
	Residual solvents	Methylene Dichloride: Not more than 600 ppm	7 ppm
	(By GC)	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:

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

Activity	Prepared By	Verified By	Approved By	
Sign & Date	Jee 13/04/17	Shy304117	118/17	
Name	Mr. Jigar Patel	Mr. Suresh Singh	Mr. S. K. Srivastava	
Designation	Executive-QA	Manager-QC	Corporate Head-QA & QC	