

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	MELOXICAM (BP/EP)		Page No.: 1 of 1
Batch No.	MLX/120014	A. R. No.	FP/20/126
Batch size	134.000 Kg	Released on	28/05/2020
Manufacturing Date	May-2020	Expiry Date	Apr-2025

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Appearance	Pale yellow powder	Pale yellow powder
2.	Solubility	Practically insoluble in water, soluble in Dimethylformamide, very slightly soluble in ethanol (96 per cent).	Complies
3.	Identification	IR spectrum: It should be concordant with Reference/working standard of meloxicam	Complies
4.	Related Substances (By HPLC)	Impurity A at 350 nm: Not more than 0.1%	Below Detection Limit
		Impurity B at 260 nm: Not more than 0.1%	Below Quantification Limit
		Impurity C at 350 nm: Not more than 0.05%	Not Detected
		Impurity D at 350 nm: Not more than 0.05%	Not Detected
		Unspecified impurities at 260/350 nm: Not more than 0.10%	Below Detection Limit
		Total impurities: Not more than 0.3%	Complies*
5.	Loss on Drying	Maximum 0.5% w/w	0.15%
6.	Sulphated ash	Maximum 0.1% w/w	0.02%
7.	Assay (By Titration)	99.0% to 101.0% (Dried substance)	99.8%
8.	Residual Solvent	Methanol: Not more than 3000 ppm	27 ppm
0.	(By GC-HS)	Ortho Xylene: Not more than 196 ppm	11 ppm

CONCLUSION:

In opinion of the undersigned, the above mentioned product COMPLIES as per BP-2019/EP-9.0/In-House Specifications. * All individual impurities are below detection limit.

STORAGE CONDITION: Preserve in well closed container, protected from light. Store at a temperature not exceeding 30 °C. Excursion allowed up to 40°C.

Activity	Prepared By	Verified By	Approved By
Sign & Date	Komel	28/05/2020.	205/2020
Name	Ms. Komal Kumari	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Officer-QA	Sr. Manager - QC	Head-QA