

## 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 (USP)		Page No.: 1 of 1
Batch No.	MLX/118046	A. R. No.	FP/18/300
Batch size	131.00 Kg	Released on	03/12/2018
Manufacturing Date	Nov-2018	Expiry Date	Oct-2023

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	Pale yellow powder.	Pale yellow powder
2.	Solubility	Soluble in Dimethylformamide; Slightly soluble in acetone; Very slightly soluble in methanol and in alcohol; Practically insoluble in water.	Complies
3.	Identification	A) <b>Infrared spectrum:</b> It should be concordant with Reference/Working Standard of Meloxicam.	Complies
		B) <b>By HPLC:</b> The retention time of the meloxicam peak of the Sample solution corresponds to that of ws/ers solution, as obtained in the Assay.	Complies
4.	Assay (By HPLC)	Not less than 98.0 % and Not more than 102.0 % of meloxicam. (Calculated on dried basis)	99.5%
<b>Impurity</b>			
5.	Residue on ignition	Not more than 0.1%	0.04%
6.	Organic Impurities (By HPLC) As per Procedure 2	Meloxicam related compound B at 260 nm: NMT 0.1%	0.003%
		Meloxicam related compound C at 350 nm: NMT 0.1%	0.01%
		Individual unknown impurity at 260/350 nm: NMT 0.1%	0.01%
		Total impurities: NMT 0.3%	0.03%
7.	Loss on Drying	Not more than 0.5% w/w	0.17%
8.	Residual solvents (By GC)	<b>Methanol:</b> Not more than 3000 ppm	28 ppm
		<b>Ortho Xylene:</b> Not more than 1000 ppm	8 ppm

**CONCLUSION:**

In opinion of the undersigned, the above mentioned product **COMPLIES** as per USP-41 Specifications.

**STORAGE CONDITION:** Preserve in well-closed containers, Store at room temperature.

Activity	Prepared By	Verified By	Approved By
Sign & Date	<i>Komal</i> 03/12/18	<i>Hemant</i> 03/12/18	<i>S.K. Srivastava</i> 03/12/18
Name	Ms. Komal Kumari	Mr. Hemant Patel	Mr. S. K. Srivastava
Designation	Officer-QA	Sr. Manager-QC	Corporate Head-QA & QC