KalChem™
INTERNATIONAL
Compounding Chemicals You Can Trust

Swati Spentose Pvt.Ltd. Unit-I
A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396195,
Gujarat. India.

Certificate Of Analysis
(Finished Product)

Product Name: Meloxicam USP

Product Name	Meloxicam USP	**A.R. No.**	SS01FP22000212
Batch No.	MLX/722004	**Date of Release**	01/07/2022 18:11
Batch Size	543.500 Kg	**Storage Condition**	NMT 30°C & Excursion upto 40°C
Mfg. Date	Jun/2022	**Exp./ Retest Date**	May/2027

S. No.	TEST	SPECIFICATION	RESULT
1	**Description**	Pale yellow powder.	Pale yellow powder.
2	**Solubility**		
2.1	**In Dimethylformamide**	Soluble in Dimethylformamide.	Soluble in Dimethylformamide
2.2	**In Acetone**	Slightly soluble in acetone.	Slightly soluble in acetone
2.3	**In Methanol**	Very slightly soluble in methanol.	Very slightly soluble in methanol.
2.4	**In Alcohol**	Very slightly soluble in alcohol.	Very slightly soluble in alcohol.
2.5	**In Water**	Practically insoluble in water.	Practically insoluble in water.
3	**Identification by Infrared Absorption (IR)**	The infrared absorption spectrum of sample should be concordant with the reference standard /Working Standard spectrum of Meloxicam.	Concordant With Working Standard
4	**Identification by HPLC**	The retention time of the meloxicam peak of the Sample solution corresponds to that of the standard solution, as obtained in the assay.	The retention time of the meloxicam peak of the sample solution corresponds to the standard Solution, as obtained in the Assay.
5	**Assay by HPLC**	Not less than 98.0% and Not more than 102.0% of Meloxicam ($C_{14}H_{13}N_3O_4S_2$). Calculated on the dried basis.	100.3 %
6	**Residue on Ignition**	Not More Than 0.1%	0.030 %
7	**Organic Impurities**		

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Analyzed By	Samson M.Kamble	Analyzed By (Role)	Samson M.Kamble (QC Analyst)	Analyzed On	01/07/2022 14:12
Checked By	Ajay.Mishra	Checked By (Role)	Ajay.Mishra (QC Head)	Checked On	01/07/2022 16:00
Approved By (QC)	Rama Murthy V R Murthy.Ayyagari	Approved By (Role)	Rama Murthy V R Murthy.Ayyagari (QC Head)	Approved On	01/07/2022 17:12
Approved By (QA)	P.N.Rao	Approved By (Role)	P.N.Rao (Quality Head)	Approved On	01/07/2022 18:11

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	Procedure 2 By HPLC		
7.1	**Related Compound B at 260 nm**	Not more than 0.1%	0.005 %
7.2	**Related Compound C at 350 nm**	Not more than 0.1%	0.026 %
7.3	**Individual unknown impurity at 260 nm**	Not more than 0.1%	0.017 %
7.4	**Individual unknown impurity at 350 nm**	Not more than 0.1%	0.019 %
7.5	**Total Impurities**	Not more than 0.3%	0.17 %
8	**Loss on Drying**	Not more than 0.5%	0.19 %
9	**Residual Solvents by GC-HS**		
9.1	**O-Xylene**	Not more than 196 ppm	8 ppm
9.2	**Methanol**	Not more than 3000 ppm	65.50 ppm
10	**Bulk Density**	Informative	Untapped Density - 0.29 g/ml Tapped Density - 0.67 g/ml
11	**Particle Size**	100% passing through 40 mesh.	99.98 %
12	**Foreign & Black Particles**	Should be free from foreign and black particles	Free From Foreign and Black Particles
13	**Polymorphic Identity (By X-Ray powder diffraction)**	The X-Ray power diffraction pattern of sample conforms to the X-Ray powder diffraction pattern of Meloxicam USP Working Standard (Form-I).	The X-Ray Powder Diffraction Pattern Of Sample Conforms To The X-Ray Powder Diffraction Pattern Of Meloxicam Working Standard(Form-1)

Remarks: APPROVED (Sample Conforms to above Specification)

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14	**Particle Size (By Malvern Particle Size Analyser)**	Informative	D (0.1) - 5.519 MICRON D (0.5) - 15.015 MICRON D (0.9) - 28.946 MICRON
15	**Bacterial Endotoxin**	Informative	less than 1.1 EU/mg
16	**Total aerobic microbial count**	Not more than 10^3 Cfu/g	20 CFU / g
17	**Total combined yeast and mold count**	Not more than 10^2 Cfu/g	Nil
18	**Escherichia Coli**	should be absent in 1g	Absent in 1 g
19	**Salmonella abony**	should be absent in 10g	Absent in 10 g
20	**Pseudomonas aeruginosa**	should be absent in 1g	Absent in 1 g
21	**Staphylococcus aureus**	should be absent in 1g	Absent in 1 g

Test Plan Remarks: Storage Condition : Preserve in well closed container, protected from light. Store at a temperature not exceeding 30?. Excursion allowed up to 40°C.

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