



UNICHEM
LABORATORIES LTD.

Plot No. 99, M.I.D.C., Dhatav, Roha, Dist. Raigad - 402 116. (India)

Phone : + 91-2194-263561, 62, 49.

Fax : + 91-2194-263545.

Certificate of Analysis

Product: PIROXICAM USP

Batch No.	RPCP210034	LIMS A.R. No.	ROFP2200896
Mfg. Date	Oct-2021	Product Code	10000649
Exp. Date/Retest-date	Sep-2026	Batch Quantity	6.616 Kg
Specification Id	GA/APIS/PRC01/8.00	Date Of Release	May 10, 2022
STP No.	GA/APISTP/PRC01/6.00	Customer/Country	SUAN FARMA

1110922

S. No.	TEST	SPECIFIED	ACTUAL
1	Description	Off white to light tan or light yellow, odourless powder	Off white odourless powder
2	Solubility	Soluble in methylene chloride, Slightly soluble in 0.1N sodium Hydroxide, insoluble in water and in anhydrous ethanol.	Soluble in methylene chloride, Slightly soluble in 0.1N sodium Hydroxide, insoluble in water and in anhydrous ethanol.
3	Identification		
3.1	By IR	The IR spectrum of the sample should be concordant with the spectrum obtained from Piroxicam reference /Working standard (Form-I)	The IR spectrum of the sample concordant with the spectrum obtained from Piroxicam Working standard (Form-I)
3.2	By UV	The UV absorption spectrum of the sample solution should match with that of similar preparation of Piroxicam reference/Working standard	The UV absorption spectrum of the sample solution match with that of similar preparation of Piroxicam Working standard
3.3	By TLC	The RF value of the principal spot obtained from the test solution should correspond to that obtained from the Piroxicam Reference/Working standard.	The RF value of the principal spot obtained from the test solution correspond to that obtained from the Piroxicam Working standard.
4	Water by KF	Not More than 0.5%w/w	0.04 %
5	Residue on ignition	NMT 0.3%w/w	0.04 %
6	Assay by HPLC	NLT 97.0%w/w and NMT 103.0%w/w	Average: 99.9 %
7	ADDITIONAL TESTS		

Remarks: APPROVED (Sample Conforms to above Specification)

Initiated By

Nivrutti.Phatangare (QC Incharge)

May 11 2022 10:40AM

Printed by: Nitin.Thamke

Copy No.: 1

Checked By

Dilip.Bonage (QC Incharge)

May 11 2022 12:33PM

Approved By

Nitin.Thamke (Manager)

May 11 2022 12:38PM

Printed on: May 11 2022 12:39PM

Page No.: 1 of 2

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UNICHEM - A TRUSTED NAME IN PHARMACEUTICALS

RQA/F/007/02



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7.1	By XRPD	The X-ray diffractogram of sample should exhibit the following characteristics 2theta values of Piroxicam Form-I and should be within the limit of ± 0.2 degree 2 theta : 8.66, 11.68, 12.52, 14.06, 14.52, 15.89, 16.71, 17.13, 17.72, 18.86, 21.77, 26.77, 27.41 and 27.81	The X-ray diffractogram of sample exhibit the following characteristics 2theta values of Piroxicam Form-I and within the limit of ± 0.2 degree 2 theta : 8.65, 11.67, 12.51, 14.05, 14.53, 15.88, 16.72, 17.14, 17.72, 18.85, 21.76, 26.77, 27.42 and 27.81
8	Related Substances (By HPLC)		
8.1	Individual unspecified impurity	NMT 0.10%w/w	Average: 0.00 %
8.2	Total impurities	NMT 0.4%w/w	Average: 0.00 %
9	Residual solvents by GC		
9.1	Methanol	NMT 3000ppm	Average: 32 ppm
9.2	Isopropyl alcohol	NMT 5000ppm	Average: 6 ppm
9.3	O-Xylene	NMT 195ppm	Average: 0 ppm
9.4	Dimethylformamide	NMT 880ppm	Average: 90 ppm

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