



UNICHEM
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Certificate of Analysis

Product: PIROXICAM USP			
Batch No.	RPCP210032	LIMS A.R. No.	ROFP2200894
Mfg. Date	Oct-2021	Product Code	10000649
Exp. Date/Retest date	Sep-2026	Batch Quantity	6.492 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

11/05/22 ✓

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	0.03 %
6	Assay by HPLC	NLT 97.0%w/w and NMT 103.0%w/w	Average: 100.2 %
7	ADDITIONAL TESTS		

Remarks: APPROVED (Sample Conforms to above Specification)

Initiated By	Checked By	Approved By
Nivrutti.Phatangare (QC Incharge)	Dilip.Bonage (QC Incharge)	Nitin.Thamke (Manager)
May 11 2022 10:41AM	May 11 2022 12:32PM	May 11 2022 12:38PM
Printed by: Nitin.Thamke	Printed on: May 11 2022 12:40PM	
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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 : 8.64, 11.67, 12.50, 14.05, 14.52, 15.87, 16.72, 17.13, 17.72, 18.84, 21.76, 26.77, 27.42 and 27.80
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: 35 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: 73 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

Initiated By Nivrutti.Phatangare (QC Incharge) May 11 2022 10:41AM	Checked By Dilip.Bonage (QC Incharge) May 11 2022 12:32PM	Approved By Nitin.Thamke (Manager) May 11 2022 12:38PM
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