



# Saurav Chemicals Limited

Corporate Office: Plot No. 370, Industrial Area, Phase-II Panchkula-134109,  
(Haryana) INDIA

<b>CERTIFICATE OF ANALYSIS</b>			
<b>KETOPROFEN – USP</b>			
Batch No.	KTF230014	Mfg. Date	April - 2023
Batch Qty.	169.81 Kg	Retest. Date	March - 2026
A.R.No.	KTFD230014	Date of analysis	13-Jul-23

  

TESTS	RESULTS	SPECIFICATIONS
01. Description*	White crystalline powder.	White or almost white, crystalline powder.
02. Solubility*	Practically insoluble in water, freely soluble in acetone, in ethanol (96%) and in methylene chloride.	Practically insoluble in water, freely soluble in acetone, in ethanol (96%) and in methylene chloride.
03. Identification a. By IR	The IR absorption spectrum of sample is match with the reference spectrum of the Ketoprofen WS.	The IR absorption spectrum of sample should match with the reference spectrum of the Ketoprofen RS/WS.
b. UV Absorption(%)	0.75	Not more than 3.0
04. Melting range (°C)	94.1 – 95.2	92.0 – 97.0
05. Optical Rotation (°)	+0.30	+1 to -1
06. Loss on Drying (under vacuum 60°C, 4 hr) %w/w	0.20	Not more than 0.5
07. Residue on Ignition %w/w	0.04	Not more than 0.2

  

Prepared By / Date <i>Re 02-Aug-23</i>	Checked By / Date <i>Re 02-Aug-23</i>	Approved By / Date <i>A 02-Aug-23</i>
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Mfd. By: Saurav Chemicals Limited, Derabassi-Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India.



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TESTS	RESULTS	SPECIFICATIONS
<b>08. Organic Impurities by HPLC (%)</b>		
8.1 Any Individual Impurity	0.07	Not more than 0.2
8.2 Total Impurities	0.15	Not more than 1.0
<b>09. Assay (By titration) (on dried basis) (%w/w)</b>	99.6	Between 98.5 to 101.0
<b>10. Residual solvents (by GC-MS) (ppm)(OVI-I)</b>		
a. Methanol	BQL	Not more than 3000
b. Ethyl Acetate	BDL	Not more than 5000
c. Toluene	68	Not more than 890
d. Cyclohexane	BQL	Not more than 3880
e. Isopropyl alcohol	Not Detected	Not more than 5000
<b>11. Residual solvents (by GC-MS) (ppm) (OVI-II)</b>		
a. Benzene	Not Detected	Not more than 2
<b>12. Acetic acid content (By HPLC) (ppm)</b>	BDL	Not more than 5000
<b>13. Particle Size Distribution by Malvern Mastersizer (Dry method) <math>\mu\text{m}</math></b>		
D (v,0.95)	9	Not more than 20
<b>Report:</b> The product complies with respect USP specification.		
Prepared By / Date <i>P</i> 02-Aug-23	Checked By / Date <i>B</i> 02-Aug-23	Approved By / Date <i>A</i> 02-Aug-23

\*Description and solubility is incorporated as per EP.

Mfd. By: Saurav Chemicals Limited, Derabassi-Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India.