

UNIQUE CHEMICALS

(A Division of J. B. Chemicals & Pharmaceuticals Ltd).
Plot no.5, Phase IV, GIDC Industrial Estate, PANOLI (GUJARAT) INDIA.

CERTIFICATE OF ANALYSIS

QUALITY CONTROL DEPARTMENT

Name of the Product	: DICLOFENAC ACID		
Name of the manufacturer	: UNIQUE CHEMICALS, PANOLI.		
Batch No.	: PDFA130091	A.R. No.	: 09FP13001045
Manufacturing Date	: Aug-2013	Expiry Date	: Jul-2018
		Release Date	: 21/08/2013

TESTS	RESULTS	STANDARDS
Description	White crystalline powder	A white to slightly yellowish, crystalline powder.
Solubility	Freely soluble in Dimethyl Formamide and in Dimethyl Sulphoxide, Soluble in acetone and methanol, sparingly soluble in ethanol, practically insoluble in water.	Freely soluble in Dimethyl Formamide and in Dimethyl Sulphoxide, Soluble in acetone and methanol, sparingly soluble in ethanol, practically insoluble in water.
Melting Point	It melts at 169°C with decomposition.	It melts at about 170°C with decomposition.
Identification: A: Infrared spectrum B: TLC	A: The infra-red spectrum of sample is concordant with the spectrum obtained from Diclofenac Acid working standard. B: The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution.	A: The infra-red spectrum of sample should be concordant with the spectrum obtained from Diclofenac Acid working standard. B: The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution.
Loss on drying (100°C to 105°C for 3 hours)	0.21% w/w	Not more than 0.5 % w/w
Appearance of 5 % Acetonic solution.	Solution is clear and not more intensely coloured than reference solution BY6	Solution should be clear and not more intensely coloured than reference solution BY6
Heavy metals	Less than 10 ppm	Not more than 10 ppm.
Related substances. (By HPLC) A: Diclofenac Impurity A B: Any other impurity C: Total impurities	0.02% 0.01% 0.03%	A: Not more than 0.15 % B: Not more than 0.10 % C: Not more than 0.3 %
Residue on ignition	0.07% w/w	Not more than 0.1% w/w
Assay (By HPLC) (On dried basis)	99.4 % w/w	98.0 % w/w to 102.0 % w/w
Additional Test:		
Particle size (By Sympatec)	10% < 2.3 µm, 50% < 9.7 µm, 90% < 26.1 µm, 99% < 44.0 µm, 100% < 72.0 µm	Min. 10% < 3 µm, Min. 50% < 10 µm, Min. 90% < 35 µm, Min. 99% < 95 µm, 100% < 146 µm

Abbreviation: TLC = Thin Layer Chromatography, HPLC = High Performance Liquid Chromatography.

Prepared By/Date	Checked By/Date	Approved By/Date
 22/08/13	 22-08-13	 22/08/2013