

UNIQUE CHEMICALS

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

QUALITY CONTROL DEPARTMENT

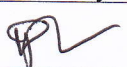
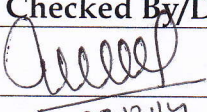
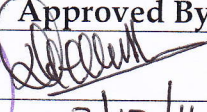
CERTIFICATE OF ANALYSIS

| | | | |
|--------------------------|-----------------------------|--------------|----------------|
| Name of the Product | : DICLOFENAC ACID | | |
| Name of the manufacturer | : UNIQUE CHEMICALS, PANOLI. | | |
| Batch No. | : PDFA140107 | A.R. No. | : 09FP14001774 |
| Manufacturing Date | : Nov-2014 | Expiry Date | : Oct-2019 |
| | | Release Date | : 29/11/2014 |

| 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 168.6°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) | 0.22% 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 20 ppm | Not more than 20 ppm. |
| Related substances. (By HPLC) A: Diclofenac Impurity A B: Any other impurity C: Total impurities | BQL (LOQ=0.02%) 0.03% 0.04% | 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) | 99.9 % w/w | 98.0 % w/w to 102.0 % w/w |
| Additional Test: | | |
| Particle size (By Sympatec) | 10% < 2.6 µm, 50% < 15.0 µm, 90% < 51.6 µm, 99% < 89.9 µm, 100% < 146.0 µm | For Information. |

Abbreviation: TLC = Thin Layer Chromatography, HPLC = High Performance Liquid Chromatography.
BQL = Below Quantitation Limit, LOQ = Limit of Quantitation

OPNION: The above batch of DICLOFENAC ACID complies with the prescribed standards of quality.

| Prepared By/Date | Checked By/Date | Approved By/Date |
|---|---|--|
|  03/12/14 |  03/12/14 |  3/12/14 |

