

UNIQUE CHEMICALS



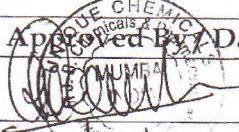
(A Division of J. B. Chemicals & Pharmaceuticals Ltd.)
Plot no-5, Phase IV, GIDC Estate, Panoli-394 116, GUJARAT, INDIA.

CERTIFICATE OF ANALYSIS QUALITY CONTROL DEPARTMENT

| | | | |
|--------------------|-----------------------------|-----------------------|----------------|
| Name of product | : DICLOFENAC SODIUM EP | | |
| Manufactured by | : Unique Chemicals, Panoli. | | |
| Batch No. | : PDFS350018 | Analytical Report No. | : 09FP15000483 |
| Manufacturing date | : Feb-2015 | Expiry date | : Jan-2020 |
| | | Release Date | : 10/03/2015 |

| TESTS | RESULTS | STANDARDS |
|---|---|---|
| Appearance | A White crystalline powder, slightly hygroscopic. | A white or slightly yellowish crystalline powder, slightly hygroscopic. |
| Solubility | Sparingly soluble in water, freely soluble in methanol, soluble in alcohol, slightly soluble in acetone. | Sparingly soluble in water, freely soluble in methanol, soluble in alcohol, slightly soluble in acetone. |
| Melting point | It melts at 276.8°C with decomposition | It melts at about 280°C with decomposition |
| Identification A: Infra red absorption Spectrophotometer | A: The IR absorption spectrum is concordant with the spectrum obtained with Diclofenac Sodium working Standard. | A: The IR absorption spectrum should concordant with the spectrum obtained with Diclofenac Sodium working Standard. |
| D: Reaction (b) of sodium | D: The solution gives reaction (b) of sodium | D: The solution gives reaction (b) of sodium |
| Appearance of solution: Clarity of solution Colour of solution (5% solution in methanol at 440 nm.) | Clear solution 0.01 | Solution should be clear Not more than 0.05 |
| Related Substances (HPLC) : Diclofenac impurity A Diclofenac impurity F Unspecified impurity Total impurities | Not Detected Not Detected BDL BDL | Not more than 0.2% Not more than 0.15% Not more than 0.10% Not more than 0.4% |
| Heavy metals | Less than 10 ppm | Not more than 10 ppm |
| Loss on drying | 0.23% w/w | Not more than 0.5 % w/w |
| Assay (On dried basis) | 99.9% w/w | 99.0% w/w to 101.0% w/w |
| Additional tests: | | |
| Particle Size (By Sympatec analyzer) | 95 % < 18.6 µm 100 % < 79.0 µm | Min. 95 % < 50 µm 100 % < 125 µm |
| Diclofenac Sodium Dimer (By HPLC) | Not Detected | Not more than 0.1% |
| Note: BDL - Below Disregard Limit (< 0.05%) | | |

OPINION: The above sample complies with the prescribed standards of quality as per EP and the requirements of certificate of suitability no. R1-CEP 1997-041-Rev 04.

| Prepared By / Date | Checked By / Date | Approved By / Date |
|---|---|---|
|  19/03/15 |  19/03/2015 |  19/03/2015 |