

UNIQUE CHEMICALS

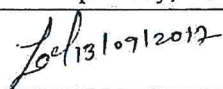
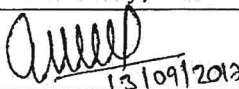
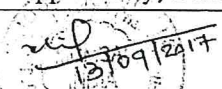
(A Division of J. B. Chemicals & Pharmaceuticals Ltd.)
Plot no-5, Phase IV, GIDC Estate, Panoli-394 116, GUJARAT, INDIA.

CERTIFICATE OF ANALYSIS QUALITY CONTROL DEPARTMENT

Name of product	: DICLOFENAC SODIUM EP		
Manufactured by	: Unique Chemicals, Panoli.		
Batch No.	: PDFS170086	Analytical Report No.	: 09FP17001851
Manufacturing date	: Jul-2017	Expiry date	: Jun-2022
		Release Date	: 11/09/2017

TESTS	RESULTS	STANDARDS
Characters		
Appearance	A white slightly hygroscopic, crystalline powder.	A white or slightly yellowish, slightly hygroscopic, crystalline powder.
Solubility	Sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96%), slightly soluble in acetone.	Sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96%), slightly soluble in acetone.
Melting point	It melts at 277.7°C with decomposition	It melts at about 280°C with decomposition
Identification A: Infra red absorption Spectrophotometry D: Reaction (b) of sodium salt	A: The IR absorption spectrum is concordant with the spectrum obtained with Diclofenac Sodium working Standard. D: The solution gives reaction (b) of sodium	A: The IR absorption spectrum should concordant with the spectrum obtained with Diclofenac Sodium working Standard. D: The solution should gives reaction (b) of sodium
Appearance of solution: Clarity of solution Light absorbance (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 (105°C for 3 hrs)	0.20 % w/w	Not more than 0.5 % w/w
Assay (On dried basis)	100.5 % w/w	99.0% w/w to 101.0% w/w
Additional tests:		
Particle Size (By Sympatec analyzer)	95 % < 18.4 µm 100 % < 66.0µm	Minimum 95 % < 50 µm 100 % < 125 µm
Related Substances(In-house method by HPLC) - DCDPA - Dimer	Below Detection Limit (LOD=0.0042%) 0.01 %	Not more than 0.1 % Not more than 0.1 %
Note: BDL - Below Disregard Limit (< 0.05%), LOD= Limit of Detection.		

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 05.

Prepared By / Date	Checked By / Date	Approved By / Date
 Kishor Lad (Sr. Executive QC)	 Rakesh Kushwaha (Asst. Manager QC)	 Alpesh Patel (Head QC)