

UNIQUE CHEMICALS

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

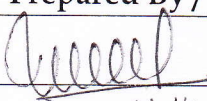
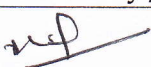
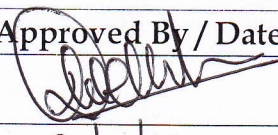
CERTIFICATE OF ANALYSIS QUALITY CONTROL DEPARTMENT

Name of product	: DICLOFENAC SODIUM EP		
Manufactured by	: Unique Chemicals, Panoli.		
Batch No.	: PDFS340096	Analytical Report No.	: 09FP14001739
Manufacturing date	: Oct-2014	Expiry date	: Sep-2019
		Release Date	: 19/11/2014

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 279.9°C with decomposition	It melts at about 280°C with decomposition
Identification A: IR Spectrum	A: The infra-red spectrum of sample is concordant with the spectrum obtained from Diclofenac sodium working standard.	A: The infra-red spectrum of sample should concordant with the spectrum obtained from Diclofenac sodium working standard.
D: Reaction (b) of sodium salt	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	0.19% w/w	Not more than 0.5 % w/w
Assay (On dried basis)	100.4% w/w	99.0% w/w to 101.0% w/w
Additional tests:		
Particle Size (By Sympatec analyzer)	95 % < 37.8 µm 100 % < 112.0 µm	Minimum 95 % < 50 µm Minimum 100 % < 125 µm
Diclofenac Sodium Dimer (By HPLC)	BQL (LOQ=0.01%)	Not more than 0.1%

Note: BDL – Below Disregard Limit (< 0.05%), BQL- Below Quantitation Limit, LOQ- Limit of Quantitation.

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 03.

Prepared By / Date	Checked By / Date	Approved By / Date
 21.11.14	 21.11.14	 21/11/14