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.	: PDFS320088	A.R. No.	: 09FP12001366
Manufacturing Date	: Nov-2012	Expiry Date	: Oct-2017
		Release Date	: 23/12/2012

TESTS	RESULTS	STANDARDS
Appearance	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 281° C with decomposition	It melts at about 280°C with decomposition
Identification A: IR Spectrum D: Reaction (b) of sodium salt	 A: The infra-red spectrum of sample is concordant with the spectrum obtained from Diclofenac sodium working standard. D: The solution gives reaction (b) of sodium	 A: The infra-red spectrum of sample should concordant with the spectrum obtained from Diclofenac sodium working standard. D: The solution gives reaction (b) of sodium
Appearance of solution: Clarity of solution Colour of solution	 Clear solution 0.02	 Solution should be clear E at 440 Maximum 0.05 (5% w/v)
Related Substances (HPLC) : Diclofenac impurity A Diclofenac impurity B Diclofenac impurity C Diclofenac impurity D Diclofenac impurity E Any other impurity Total impurities	 Not Detected 0.02% Not Detected Not Detected Not Detected 0.04% 0.07%	 Not more than 0.2% Not more than 0.2% Not more than 0.2% Not more than 0.2% Not more than 0.2% Not more than 0.10% Not more than 0.5%
Heavy metals	Less than 10 ppm	Not more than 10 ppm
Loss on drying	0.18 % w/w	Not more than 0.5 % w/w
Assay (On dried basis)	100.0 % w/w	99.0% w/w to 101.0% w/w
Additional tests:		
Particle Size (By Sympatech)	72 % < 7.4 µm 84 % < 12.4 µm 98 % < 30.0 µm	Minimum 70 % < 20 µm, Minimum 85 % < 40 µm, Minimum 97 % < 100 µm.
Diclofenac Sodium Dimer (By HPLC)	Not Detected	Not more than 0.1 %

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
24/12/12	24.12.12	24/12/12