

UNIQUE CHEMICALS

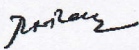


(A Division of J. B. Chemicals & Pharmaceuticals Ltd.)
Plot no. 5, Phase IV, GIDC Estate, Panoli-394 116 (GUJARAT) INDIA.

CERTIFICATE OF ANALYSIS QUALITY CONTROL DEPARTMENT

Name of product	: DICLOFENAC SODIUM EP		
Manufactured by	: Unique Chemicals, Panoli.		
Batch No.	: PDFS130201	A.R. No.	: 09FP13001581
Manufacturing Date	: Dec-2013	Expiry Date	: Nov-2018
		Release Date	: 20/12/2013

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	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	Clear solution 0.01	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 Not Detected Not Detected Not Detected Not Detected 0.01 % 0.02 %	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	0.19 % w/w	Not more than 0.5 % w/w
Assay (On dried basis)	99.6 % w/w	99.0 % w/w to 101.0 % w/w
Additional tests:		
Particle Size (By Sympatech)	95 % < 16.8 µm 100 % < 42.0 µm	Minimum 95 % < 50 µm, Minimum 100 % < 125 µm.
Diclofenac Sodium Dimer (By HPLC)	0.01 %	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
 20.12.13	 26/12/13	 26/12/2013