

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.	: PDFS350020	Analytical Report No.	: 09FP15000517
Manufacturing date	: Feb-2015	Expiry date	: Jan-2020
		Release Date	: 15/03/2015

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 276.7°C with decomposition	It melts at about 280°C with decomposition
Identification A: Infra red absorption Spectrophotometer D: Reaction (b) of sodium	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 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	0.11% w/w	Not more than 0.5 % w/w
Assay (On dried basis)	100.2% w/w	99.0% w/w to 101.0% w/w
Additional tests:		
Particle Size (By Sympatec analyzer)	95 % < 22.3 µm 100 % < 50.0 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
<u>188</u> 19/03/15	<u>215</u> 19/03/2015	 19/03/2015