

WRS

D48-7

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Amoli
Organics



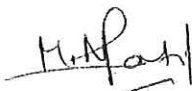
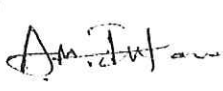

WORKING STANDARD CERTIFICATE OF ANALYSIS

Product Name: DICLOFENAC SODIUM BP	Mfg. Date: Sept. 2014	Released Date : 19/09/2015
Batch Number: DS/1409/03324	Exp. Date: Aug. 2019	Use before : 19/09/2016
Quantity: 1.0gram		A.P. No. : ADS/14/0407

TEST	OBSERVATION	SPECIFICATION
Appearance	Almost white crystalline powder, slightly hygroscopic.	A white or slightly yellowish slightly hygroscopic, crystalline.
Solubility	Complies	Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.
Melting Point	280 ⁰ C to 281.5 ⁰ C	It melts at about 280 ⁰ C, with decomposition.
Identification (A) By IR spectrophotometer	Conformed	The infrared absorption spectrum of the sample must be concordant with that of Diclofenac sodium reference/working standard spectrum.
(D) Reaction of sodium (b)	Conformed	No precipitate is formed.
Appearance of solution Ab. 5% In MeOH/440nm/1cm	Complies 0.027	The solution is Clear. Not more than 0.05
Related substances (By HPLC)		
Impurity-A	Below Detection Limit	Not more than 0.2%
Impurity-F	0.003%	Not more than 0.15%
Unspecified Impurity	0.01%	Not more than 0.10%
Total impurities	0.02%	Not more than 0.4%
Heavy metals	Less than 10 ppm	Not more than 10 ppm
Loss on drying (At 105 ⁰ C for 3 hrs)	0.28% (w/w)	Not more than 0.5% (w/w)
Assay (Calculated on dried basis)	99.88% (w/w)	Not less than 99.0% and Not more than 101.0% (w/w)

Related substances: Limit of Detection for impurity-A: 0.001% & Impurity-F: 0.0009%

Conclusion: The sample Complies as per BP.

	Prepared By	Checked By	Released for Dispatch
Sign & Date			
Name & Designation	M.N. Patel, Asst. Mgr.-QC	A.M. Intwala, Asst. Mgr.-QC	R.K. Ahir, Mgr.-QA

SOP No.: VQC/O/006

Format No.: VQC/F/089-00

DS-Triveni formulation, India-SO 0845-580-IOM/14/0522

