



Amoli Organics Pvt. Ltd.

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6-27-0218

Lot: 0110914

CERTIFICATE OF ANALYSIS

Product Name : DICLOFENAC SODIUM Ph.Eur. (CEP Grade-Bromine free)		Sampling Date : 21/06/2014	
Batch No.: RDS/1406/0166A	Mfg. Date : Jun. 2014	Released Date : 30/06/2014	
Batch Size : 835.37 Kgs.	Exp. Date : May 2019	A.R. No. : ARDS/14/0188	
TEST	OBSERVATION	SPECIFICATION	
Appearance	Almost white crystalline powder, slightly hygroscopic	A white or slightly yellowish slightly hygroscopic, crystalline powder.	
Solubility	Complies	Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96% , slightly soluble in acetone,	
	280.2°C to 281.4°C	It melts at about 280°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 0.026	The solution is clear. Not more than 0.05	
Related substances (By HPLC)	0.01 % 0.01 % 0.02 %	Impurity-A Not more than 0.2 % Unspecified Imp. Not more than 0.10 % Total impurities Not more than 0.5 %	
Heavy metals	Less than 10 ppm	Not more than 10 ppm	
Loss on drying (At 105°C for 3 hrs)	0.31 % (w/w)	Not more than 0.5 % (w/w)	
Assay (Calculated on dried basis)	99.6 % (w/w)	Not less than 99.0 % and Not more than 101.0 % (w/w)	
Additional In-House test			
EDTA Content	Below Detection Limit	Not more than 10 ppm	
Residual solvents 2- Propanol Toluene	Below Detection Limit Below Detection Limit	Not more than 1000 ppm Not more than 100 ppm	
Conclusion : The sample Complies as per Ph.Eur. & Additional In-house Test.			
Sign & Date Name & Designation	Prepared By	Checked By	Released for Dispatch
	 M.N.Patel, Asst.Mgr.-QC	 R.D.Mehta, Mgr.-QC	 A.S.Desai, Exe.-QA
SOP No. : VQC/O/006		Format No. : VQC/F/089-00	
RDS-R2 Pharmactive, Denmark-Exp-0218-100-IOM/14/0347			