




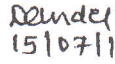

Amoli Organics Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

Product Name : DICLOFENAC SODIUM Ph.Eur. (CEP Grade)		Sampling Date : 02/04/2016	
Batch No.: RDS/1603/0087A	Mfg. Date : Mar. 2016	Released Date : 09/04/2016	
Batch Size : 861.51 Kgs.	Exp. Date : Feb. 2021	A.R. No. : ARDS/16/0091	
TEST	OBSERVATION	SPECIFICATION	
Appearance	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,	
Melting Point	279.3°C to 281.2°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 0.019	The solution is clear. Not more than 0.05	
Related substances (By HPLC)			
Impurity-A	0.01%	Not more than 0.2 %	
Impurity-F	Below Detection Limit	Not more than 0.15 %	
Unspecified Impurity	0.004%	Not more than 0.10 %	
Total Impurities	0.01 %	Not more than 0.4 %	
Heavy metals	Less than 10 ppm	Not more than 10 ppm	
Loss on drying (At 105°C for 3 hrs)	0.30 % (w/w)	Not more than 0.5 % (w/w)	
Assay (Calculated on dried basis)	99.7 % (w/w)	Not less than 99.0 % and Not more than 101.0 % (w/w)	
Additional In-House test / Customer Requirement			
Particle size (By Sieve)	100 %	100 % passing through 20 mesh	
EDTA Content	Below Detection Limit	Not more than 10 ppm	
Residual solvents			
2- Propanol	Below Detection Limit	Not more than 1000 ppm	
Toluene	Below Detection Limit	Not more than 100 ppm	
*Related substances : Limit of Detection for impurity-A : 0.001 % & Impurity-F : 0.0009 %			
*Residual Solvents : Limit of Detection for 2-Propanol : Below 3.13 ppm & Toluene : 2.23 ppm			
Conclusion : The sample Complies as per Ph.Eur., Additional In-house Test & Customer Test Specification.			
Sign & Date Name & Designation	Prepared By	Checked By	Released for Dispatch
	 M.R.Bhandari, Exe.-QC	 D.D.Tandel, Sr.Exe.-QC	 R.K.Ahir, Mgr.-QA
SOP No. : VQC/O/006		Format No. : VQC/F/089-00	
RDS-Caldic Denmark.Denmark-EXP-00268-50			