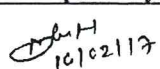
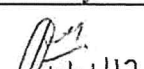
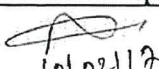




Amoli Organics Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

Product Name: DICLOFENAC SODIUM Ph.Eur. (COS Grade)		Sampling Date : 29/08/2016
Batch No.: RDS/1608/0194A	Mfg. Date : Aug. 2016	Released Date : 03/09/2016
Batch Size : 862.74 Kgs.	Exp. Date : Jul. 2021	A.R. No. : ARDS/16/0211
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	280.2°C to 281.6°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 0.017	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	Below Detection Limit	Not more than 0.15 %
Unspecified Impurity	0.02 %	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°C for 3 hrs)	0.28 % (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		
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 SOP No. : VQC/O/006	Prepared By  M. R. Patel, Officer -QC	Checked By  R.D. Mehta, Mgr.-QC
	Released for Dispatch  A.N. Nehate, Asst. Mgr.-QA Format No. : VQC/F/089-00 RDS-Caldic Denmark.Denmark-EXP-0904-50	