



Amoli Organics Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

Product Name : DICLOFENAC DIETHYLAMINE BP		Sampling Date: 07/08/2016	
Batch No. : RDDA/1608/0007A	Mfg. Date : Aug. 2016	Release Date : 12/08/2016	
Batch Size : 860.91 Kgs.	Exp. Date : Jul. 2021	A. R. No. : ARDDA/16/0009	
TEST	OBSERVATION	SPECIFICATION	
Characteristics	Light beige crystalline powder	A White to light beige, crystalline powder.	
Solubility	Complies	Sparingly soluble in water and in acetone; freely soluble in ethanol (96%) and in methanol; practically insoluble in 1M Sodium hydroxide.	
Melting Point	150.5°C to 152.4°C	It melts at about 154°C with decomposition	
Identification			
(A) By IR spectrophotometry	Conformed	The Infrared absorption spectrum of the sample must be concordant with that of Diclofenac Diethylamine reference /working standard spectrum. The two principal spot in the chromatogram obtained with solution(1) are similar in position, colour and size to the corresponding spots in the chromatogram obtained with solution (2)	
(B) By TLC	Conformed		
Acidity or Alkalinity-pH (1 % w/v solution in 10 % Ethanol)	7.19	Between 6.4 – 8.4	
Clarity & colour of solution Absorbance of solution (5% w/v in Methanol/440 nm/1cm)	Complies 0.012	Clear Solution Not more than 0.05	
Heavy metals	Less than 10 ppm	Not more than 10 ppm	
Related substances(By HPLC)			
Impurity-A	0.004 %	Not more than 0.2 %	
Impurity-F	Below Detection Limit	Not more than 0.15 %	
Unspecified Impurity	0.07 %	Not more than 0.10 %	
Total Impurities	0.10 %	Not more than 0.4 %	
Loss on drying (When dried at a pressure not exceeding 1kPa for 24 hours)	0.30 % (w/w)	Not more than 0.5 % (w/w)	
Sulfated ash	0.06 % (w/w)	Not more than 0.1 % (w/w)	
Assay (Potentiometric) (On dried basis)	99.7 % (w/w)	Not less than 99.0 % to Not more than 101.00 % w/w	
Additional In-house Test			
Residual solvents			
2- Propanol	Below Detection Limit	Not more than 5000 ppm	
Toluene	Below Detection Limit	Not more than 890 ppm	
Benzene (Impurity of Toluene)	Below Detection Limit	Not more than 2 ppm	
*Related substances : Limit of Detection for Imp-A-0.002 %. Imp-F-0.00375 %			
*Residual Solvents : Limit of Detection for 2-Propanol & Toluene : Below 1.56 ppm & Benzene : Below 0.22 ppm			
Conclusion : The sample Complies as per BP & Additional In-house Test.			
Sign & Date, Name & Designation	Prepared By	Checked By	Released for Dispatch
	 06/10/16 D.D.Tandel, Sr. Exe. -QC	 06/10/16 R.D.Mehta, Mgr.-QC	 06/10/16 R.K.Ahir, Mgr.-QA
SOP No. VQC/0/006		Format No. VQC/E/089-00	
RDDA-Caldic Denmark-Denmark.Exp0491-150			