



Amoli Organics Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

Product Name: CLOTRIMAZOLE Ph.Eur.		Sampling Date : 30/09/2019	
Batch No. : CLT/1909/0062A		Mfg. Date : Sep-2019	
Batch Size : 209.41 Kgs.		Released Date : 07/10/2019	
Exp. Date : Aug-2024		A.R. No. : ACLT/19/0110	
TEST	OBSERVATION	SPECIFICATION	
Appearance	White crystalline powder	White or pale yellow, crystalline powder.	
Solubility	Complies	Soluble in ethanol (96%) and in methylene chloride, & Practically insoluble in water.	
Identification (A) By Melting Point (B) By IR Spectroscopy (C) By TLC	142.3°C to 144.4°C Complies Complies	Melting point 141°C to 145°C The Infrared absorption spectrum of the sample must be concordant with that of Clotrimazole reference/working standard spectrum. The principal spot in the chromatogram obtained with the test solution is similar in position & size of the principal spot in the chromatogram obtained with reference solution.	
Related Substances (By HPLC)	0.06 % Below Quantitation Limit Below Quantitation Limit Below Detection Limit Below Detection Limit 0.07 % 0.13 %	Impurity-A Not more than 0.2 % Impurity-B Not more than 0.2 % Impurity-D Not more than 0.2 % Impurity-E Not more than 0.2 % Impurity-F Not more than 0.1 % Unspecified Impurities Not more than 0.10 % Total Impurities Not more than 0.5 %	
Loss on drying (At 105°C)	0.13 % (w/w)	Not more than 0.5 % (w/w)	
Sulphated Ash	0.06 % (w/w)	Not more than 0.1 % (w/w)	
Assay (Calculated on dry basis)	99.3 % (w/w)	Not less than 98.5 % and Not more than 100.5 % w/w	
Additional In-House Test			
Residual solvents Acetone Toluene Triethylamine Benzene	3070 ppm Below Detection Limit Below Detection Limit Below Detection Limit	Not more than 5000 ppm Not more than 890 ppm Not more than 50 ppm Not more than 2 ppm	
* Related substances : Limit of Detection for -Imp-A-0.02%, Imp-B-0.02%, Imp-D-0.01%, Imp-E-0.02%, Imp-F-0.02%, & Unspecified Impurity-0.02 % Limit of Quantitation for -Imp-A-0.05%, Imp-B-0.05%, Imp-D-0.04%, Imp-E-0.05%, Imp-F-0.05%, Unspecified Impurity-0.05 %			
*Residual Solvents : Limit of Detection for Acetone-11.84 ppm, Triethylamine-4.27 ppm, Toluene-15.21 ppm, Benzene-0.19 ppm Limit of Quantitation for Acetone-35.88 ppm, Triethylamine-12.94 ppm, Toluene-46.09 ppm, Benzene-0.57 ppm			
Conclusion : The Sample complies as per Ph.Eur. & Additional in-house test.			
Sign & Date Name & Designation	Prepared By	Checked By	Released for Dispatch
	 D.D.Tandel, Sr. Exe.-QC	 R.D.Mehta, Mgr.-QC	 A.N.Nehate, Asst. Mgr.-QA
SOP No. : VQC/O/006		Format No. : VQC/F/089-00	
CLT-Fagron Services, Netherlands-EXP'0481-50-0260/19			