



Amoli Organics Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

Product Name: CLOTRIMAZOLE Ph.Eur. (CEP Grade)		Sampling Date : 15/06/2020	
Batch No. : CLT/2006/0030A	Mfg. Date : Jun-2020	Released Date : 28/06/2020	
Batch Size : 290.50 Kgs.	Exp. Date : May-2025	A.R. No. : ACLT/20/0053	
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	142.8°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)	0.07 % Below Quantitation Limit Below Detection Limit Below Detection Limit Below Quantitation Limit Below Quantitation Limit 0.07 %	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)	0.17 % (w/w)	Not more than 0.5 % (w/w)	
Sulphated Ash	0.05 % (w/w)	Not more than 0.1 % (w/w)	
Assay (Calculated on dry basis)	99.6 % (w/w)	Not less than 98.5 % and Not more than 100.5 % w/w	
Additional In-House Test			
Residual solvents			
Acetone	2486 ppm	Not more than 5000 ppm	
Toluene	91 ppm	Not more than 890 ppm	
Triethylamine	Below Detection Limit	Not more than 50 ppm	
Benzene	Below Detection Limit	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. 9.0 & Additional in-house test.			
Sign & Date Name & Designation SOP No. : VQC/O/006	Prepared By	Checked By	Released for Dispatch
	 D.D.Tandel, Sr. Exe.-QC	 R.D.Mehta, Mgr.-QC	 A.N.Nehate, Asst. Mgr.-QA
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