



Amoli Organics Pvt. Ltd.

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Director Técnico

CERTIFICATE OF ANALYSIS

Product Name: CLOTRIMAZOLE Ph.Eur.(CEP Grade)	Sampling Date : 20/01/2016		
Batch No. : CLT/1601/0007A	Mfg. Date : Jan. 2016		
Batch Size : 219.81 Kgs.	Released Date : 22/01/2016		
Exp. Date : Dec. 2020	A.R. No. : ACLT/16/0010		
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	142.7°C to 144.8°C Conformed Conformed	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)	Below Detection Limit Below Detection Limit Below Detection Limit Below Detection Limit 0.08 % 0.01 % 0.10 %	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 0.1 % Total Impurities Not more than 0.5 %	
Loss on drying (At 105°C)	0.30 % (w/w)	Not more than 0.5 % (w/w)	
Sulphated Ash	0.07 % (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	1275.62 ppm	Not more than 5000 ppm	
Toluene	57.23 ppm	Not more than 890 ppm	
Triethylamine	Below Detection Limit	Not more than 50 ppm	
Benzene	Below Detection Limit	Not more than 2 ppm	
Conclusion : The Sample complies as per Ph.Eur. & Additional in-house test.			
Sign & Date Name & Designation	Prepared By	Checked By	Released for Dispatch
	 22/01/16 D.D.Tandel, Exe.-QC	 22/01/16 A.M.Intwala, Asst. Mgr.-QC	 22/01/16 M.N.Patel, Asst. Mgr.-QA
SOP No. : VQC/O/006		Format No. : VQC/F/089-00	
CLT-Fagron Services, Netherlands-EXP 00682-50-0012/16			