

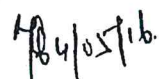


# Amoli Organics Pvt. Ltd.

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## CERTIFICATE OF ANALYSIS

Product Name: <b>CLOTTRIMAZOLE Ph.Eur.(CEP Grade)</b>		Sampling Date : 20/04/2016	
Batch No. <b>CLT/1604/0027A</b>	Mfg. Date : Apr. 2016	Released Date : 04/05/2016	
Batch Size : 222.37 Kgs.	Exp. Date : Mar. 2021	A.R. No. : ACLT/16/0037	
<b>TEST</b>	<b>OBSERVATION</b>	<b>SPECIFICATION</b>	
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	142.9°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)	0.17 % 0.02 % Below Detection Limit Below Detection Limit 0.03 % Below Detection Limit 0.22 %	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)	0.25 % (w/w)	Not more than 0.5 % (w/w)	
Sulphated Ash	0.08 % (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	
<b>Additional In-House Test</b>			
Residual solvents Acetone Toluene Triethylamine Benzene	3094.68 ppm 12.96 ppm 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	
<b>Conclusion : The Sample complies as per Ph.Eur. &amp; Additional in-house test.</b>			
Sign & Date Name & Designation	Prepared By	Checked By	Released for Dispatch
	 04/05/16 A.M. Intwala, Asst. Mgr.-QC	 04/05/16 R.D. Mehta, Mgr.-QC	 04/05/16 R.K. Ahir, Mgr.-QA
SOP No. : VQC/O/006		Format No. : VQC/F/089-00	
CLT-Fagron Services, Netherlands-EXP 0867-100-0043/16			