
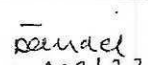





Amoli Organics Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

Product Name : CLOTRIMAZOLE USP		Sampling Date : 25/12/2021	
Batch No. : A21130J020	Mfg. Date : Dec-2021	Released Date : 31/12/2021	
Batch Size : 280.17 Kgs.	Exp. Date : Nov-2026	A.R. No. : 80000004467	
TEST	OBSERVATION	SPECIFICATION	
Description	White crystalline powder	White to pale yellow, crystalline powder.	
	142.2 °C	Melts at about 142°C. with decomposition.	
Solubility	Complies	Freely Soluble in methanol, Soluble in acetone, in chloroform, and in alcohol, Practically insoluble in water.	
Identification			
(A) By IR Spectrophotometer	Complies	The infrared absorption spectrum of the sample must be concordant with that of clotrimazole reference working standard spectrum.	
(B) By HPLC	Complies	The retention time of the major peak of the sample solution should corresponds to that the standard solution. As obtained in the test of assay.	
Loss on Drying (At 105°C for 2 hrs)	0.18 %	Not more than 0.5 % (w/w)	
Residue on ignition	0.06 %	Not more than 0.1 % (w/w)	
Limit of imidazole (By TLC)	Complies	Not more than 0.5 % (w/w)	
Limit of Clotrimazole Related Compound A (By HPLC)	0.06 %	Not more than 0.5 % (w/w)	
Assay (By HPLC) (On dried basis)	99.9 %	Not less than 98.0 % w/w and Not more than 102.0 % (w/w)	
Additional In-house Test			
Residual solvents			
Acetone	2464 ppm	Not more than 5000 ppm	
Toluene	388 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 USP 43 & Additional In-house Test.			
	Prepared By	Checked By	Released for Dispatch
Sign & Date	 18/12/22	 18/12/22	 18/12/22
Name & Designation	M.R. Bhandari, Sr. Exe.-QC	D.D. Tandel, Sr. Exe.-QC	A.N. Nehate, Mgr.-QA
SOP No : VQC/006			
Format No. : VQC/F/089-00			

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