



VIRUPAKSHA ORGANICS LIMITED

Survey No.10, Gaddapotharam Village, Jinnaram Mandal,
Sangareddy Dist.-502 319, Telangana, INDIA.

CERTIFICATE OF ANALYSIS

Name of the Product	FLUCONAZOLE EP 9.0 (COS No. RO-CEP 2009-364-Rev 01)		
Batch No.	AFLUC1018075	A.R. No.	CB/FLU-1810104
Date of Mfg.	October 2018	Retest date	September 2023
Date of analysis	20.10.2018		
S. No.	TEST	SPECIFICATION	RESULT
1.	Appearance	White or almost white, hygroscopic, crystalline powder.	White crystalline powder.
2.	Solubility	Slightly soluble in water, freely soluble in methanol, soluble in acetone.	Complies
3.	Identification by A) IR absorption	The IR spectrum of the sample should be in concordant with that of working standard.	Complies
4.	Appearance of solution	The solution is to be clear and colourless	Complies
5.	Related substances by HPLC		
	Specified impurities		
	Impurity A	Not more than 0.4 %	0.14 %
	Impurity B	Not more than 0.3 %	0.01 %
	Impurity C	Not more than 0.15 %	Not detected
	Un specified impurities	Not more than 0.10 %	0.06 %
	Total impurities	Not more than 0.6 %	0.21 %
6.	Loss on drying	Maximum 0.5 %	0.24 %
7.	Sulphated ash	Maximum 0.1 %	0.05 %
8.	Assay by potentiometry (on dried basis)	99.0 % to 101.0 %	99.7 %
9.	Residual solvents By GC (*)		
	Isopropyl alcohol	Not more than 5000 ppm	Not detected
	Methylene chloride	Not more than 600 ppm	Not detected
	Ethyl acetate	Not more than 5000 ppm	Not detected

Remarks: The product meets the requirements of EP 9.0 and (*) additional specification.

	Prepared by	Checked by	Approved by
Signature			
Date	23.10.2018	23.10.2018	23.10.2018
Name	V. Deepika	T. Balaswamy	G. Raghavendra Rao
Designation	Executive-QC	Assistant Manager-QC	General Manager- QC

Corporate office: B-4, IDA, Gandhinagar, Hyderabad-500 037, Telangana, INDIA.

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Tel : +91-40-23073417/65348442, Fax: +91-40-23720738. Email: info@virupaksha.com

QA RELEASED	
Dispatch Qty. :	5.00 kg ³
Sign :	
Date :	23.10.2018