



K Alchem International, Inc.
Compounding Chemicals You Can Trust
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VIRUPAKSHA ORGANICS LIMITED

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

CERTIFICATE OF ANALYSIS

Name of the product	FLUCONAZOLE USP 40		
Batch No.	AFLUC0518047	A.R. No.	CB/FLU-180505
Date of Mfg.	May 2018	Retest date	April 2023
Date of Analysis	23.05.2018		

S. No.	TEST	SPECIFICATION	RESULT
1.	Description	White or almost white crystalline powder	White crystalline powder
2.	Solubility	Freely soluble in methanol, soluble in alcohol and in acetone, sparingly soluble in isopropanol and in chloroform, slightly soluble in water, very slightly soluble in toluene.	Complies
3.	Clarity and color of solution	The Solution is to be clear and colorless	Complies
4.	Identification		
	a) IR absorption	To be concordant with working standard spectrum	Complies
	b) UV absorption	To be corresponds with working standard	Complies
5.	Loss on drying	Not more than 0.5 %	0.24 %
6.	Residue on ignition	Not more than 0.1 %	0.06 %
7.	Iron	Not more than 20 ppm	Less than 20 ppm
8.	Related compounds (by HPLC)		
	Impurity at RRT 0.6	Not more than 1.0 %	0.18 %
	Related compound A	Not more than 0.2 %	0.03 %
	Related compound B	Not more than 0.1 %	0.02 %
	Related compound C	Not more than 0.2 %	Not detected
	Any other individual impurity	Not more than 0.1 %	0.04 %
	Total unknown impurities	Not more than 0.3 %	0.09 %
	Total impurities	Not more than 1.5 %	0.32 %
9.	Assay (on dried basis)	98.0% to 102.0%	99.6 %
10.	Residual solvents by GC (*)		
	a) Ethyl acetate	Not more than 5000 ppm	Not detected
	b) Dichloromethane	Not more than 600 ppm	Not detected
	c) Isopropyl alcohol	Not more than 5000 ppm	Not detected

Remarks: The product meets the requirements of USP 40 and (*) additional specification.

Signature	Prepared by	Checked by	Approved by
	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	23.05.2018	23.05.2018	23.05.2018
Name	S.Nagarjuna Reddy	T.Balaswamy	G.Raghavendra Rao
Designation	QC Chemist	Assistant Manager- QC	General Manager- QC

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Page 1 of 1

QA RELEASED
Dispatch Qty.: 200.00 kg
Sign: *[Signature]*
Date: 23-05-2018