

CERTIFICATE OF ANALYSIS

Product Name	FLUCONAZOLE Ph.Eur.	Page No.	1 of 3
Batch Number	HFAC02140011	A.R. No.	14FP00081
Mfg. Date	19/01/2014	Date of Release	25/01/2014
Quantity	50.000 Kg	Retest Date	18/01/2017

S. No.	TEST	SPECIFICATION	RESULT
1	Description	White or almost white, crystalline powder.	White, crystalline powder.
2	Solubility	Slightly soluble in water, freely soluble in methanol, soluble in acetone.	Slightly soluble in water, freely soluble in methanol, soluble in acetone.
3	Identification a) By I.R.	The I.R. spectrum of sample recorded as KBr pellet should be concordant with similarly recorded spectrum of Fluconazole Crystalline Polymorph Form-III working standard.	The I.R. spectrum of sample recorded as KBr pellet is concordant with similarly recorded spectrum of Fluconazole Crystalline Polymorph Form-III working standard.
4	Appearance of solution (5 % w/v solution in methanol)	Solution should be clear and colourless.	Solution is clear and colourless.
5	Loss on drying (drying in an oven at 105 °C, determined on 1.000 g, % w/w)	Not more than 0.5 %	0.16 %
6	Sulphated ash (determined on 1.0 g, % w/w)	Not more than 0.1 %	0.05 %
7	Heavy metals (ppm)	Not more than 10 ppm	Less than 10 ppm
8	Related Substances by HPLC (% w/w) • Fluconazole isomer (Ph. Eur. Impurity A) • Tritriazole derivative (Ph. Eur. Impurity B)	Not more than 0.3 % Not more than 0.3 %	0.13 % 0.01 %

	Prepared By	Checked By	Approved By
Name	T. Appi Reddy	T. Satish Kumar	T. Venkateswara Rao
Signature			
Date	28/02/2014	28/02/2014	28/02/2014

Format No. : QC064-F01-02

AUROBINDO PHARMA LTD

Unit - VIII : Survey No. 10 & 13, Gaddapotharam Village - 502 319 IDA-Kazipally, Jinnaram Mandal, Medak District, A.P., INDIA.

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PAN No. AABCA7366H

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S. No.	TEST	SPECIFICATION	RESULT
	- Ditriazole benzene (Ph. Eur. Impurity C) - Any other - Total	Not more than 0.1 % Not more than 0.10 % Not more than 0.6 %	Below the limit of detection 0.06 % 0.20 %
9	Assay (By titrimetry, % w/w, as $C_{12}H_{12}F_2N_6O$, on dried basis)	Not less than 99.0 % and Not more than 101.0 %	100.3 %
10	Additional Tests		
	10.1 Bulk Density (g/ml)		
	- Untapped - Tapped	Report results Report results	0.29 g/ml 0.70 g/ml
	10.2 Particle Size Analysis (By Malvern particle size analyzer) (μ)		
	- D (v, 0.5) - D (v, 0.9)	$\leq 100 \mu$ $\leq 200 \mu$	54 μ 174 μ

NON-ROUTINE TEST:

11	Microbiological Limits		
	a) i. Total aerobic microbial count (TAMC)	Not more than 1000 CFU/g	Less than 10 CFU/g
	ii. Total combined yeasts/moulds count (TYMC)	Not more than 100 CFU/g	Less than 10 CFU/g
	b) Escherichia coli	Should be absent	Absent

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Chemical Names of Related Substances:

- (2RS)-2-(2,4-difluorophenyl)-1-(1H-1,2,4-triazol-1-yl)-3-(4H-1,2,4-triazol-4-yl) propan-2-ol
[Fluconazole isomer] [Ph. Eur. Impurity A]
- 2-[2-fluoro-4-(1H-1,2,4-triazol-1-yl)phenyl]-1,3-bis(1H-1,2,4-triazol-1-yl)propan-2-ol.
[Tri Triazole derivative] [Ph. Eur. Impurity B]
- 1,1'-(1,3-phenylene)di-1H-1,2,4-triazole. [Ditriazole benzene] [Ph. Eur. Impurity C]
- 2-(4-Fluorophenyl) 1,3-Bis(1H-1,2,4- Triazol-1-yl)propan-2-ol
[Desfluoro Fluconazole] [Ph. Eur. Impurity D]

REMARKS : The material complies as per the above specifications.

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