



VASUDHA PHARMA CHEM. LIMITED

Mages-pharma nu
AS: cck
78/A, Vengalrao Nagar, Hyderabad-500 038,
Telangana State, India
Phone: 91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576
E-mail: vasudha@vasudhapharma.com,
Website: www.vasudhapharma.com

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CERTIFICATE OF ANALYSIS

Name of the Product	:	ITRACONAZOLE Ph.Eur.		
Batch Number	:	CIZL/2310002	Analyzed on	: 15/02/2023
Manufacturing Date	:	FEB 2023	Retest Date	: JAN 2028
Quantity	:	153.10 Kg	A.R. No.	: FP/23042

S. No	TEST	RESULT	SPECIFICATION
1.0	Description	White powder	White or almost white powder.
2.0	Solubility	Complies	Freely soluble in methylene chloride, Very slightly soluble in ethanol (96 percent), practically insoluble in water.
3.0	Infrared absorption spectroscopy	Complies	The test spectrum should match with that of standard.
4.0	Appearance of solution	Complies	The solution S should be clear and not more intensely colored than R ₆ & B ₆
5.0	Loss on Drying (% w/w)	0.19	Not more than 0.5
6.0	Sulfated ash (% w/w)	0.06	Not more than 0.1
7.0	Assay by Potentiometry On dried basis (% w/w)	100.3	Not less than 99.0 and Not more than 101.0
8.0	Related substances by HPLC (% w/w)		
	Impurity B	Below disregard limit	Not more than 0.3
	Impurity C & Impurity D	0.05	Not more than 0.3
	Impurity E	Below disregard limit	Not more than 0.2
	Impurity G	Below disregard limit	Not more than 0.3
	Any unspecified impurity	0.06	Not more than 0.10
	Total impurities	0.19	Not more than 0.8

	Prepared By QC	Checked By QC	Approved By QC
Signature & date	 09/02/24	 09/02/24	 09/02/24
Name	P. Narasimha Rao	Ch. Narek Kumar	Sr. Narasimha
Designation	Chemist	Asst. Manager	Sr. Narasimha

Works: M/s Vasudha Pharma Chem Limited, Unit-III, Plot No:23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), Anakapalli District- 531019, Andhra Pradesh, India. Ph: 08924-236227, 236228

CQA/002/F05/01

EFFECTIVE DATE: 01/01/2021

METAPHARMACEUTICAL

N DE LOTE:

0120524

 16/03/2024

 VASUDHA PHARMA CHEM. LIMITED	VASUDHA PHARMA CHEM LIMITED 78/A, Vengalrao Nagar, Hyderabad-500 038, Telangana State, India Phone: 91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576 E-mail: vasudha@vasudhapharma.com, Website: www.vasudhapharma.com		QC. COLG Magis - pharma NV 27/03/2024 Page 2 of 2
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S.No.	TEST	RESULT	SPECIFICATION
9.0	Additional test		
9.1	Residual solvents by GC HS (ppm)		
	Methanol	BQL	Not more than 3000
	Methyl isobutyl ketone	19	Not more than 4500
	Dichloromethane	47	Not more than 600
	Toluene	BDL	Not more than 890

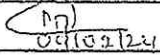
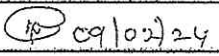
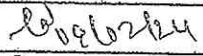
"BDL" indicates Below Detection Limit.

"BQL" indicates Below Quantification Limit.

Remarks: The material complies as per the Ph.Eur. Specification.

Transportation: Material transit in ambient condition.

Storage: Recommended to store the material at 25±2°C at your site (Excursions allowed between 15 to 30°C).

	Prepared By QC	Checked By QC	Approved By QC
Signature & date	 09/02/24	 09/02/24	 09/02/24
Name	P. Manikanta Rao	Ch. Noreli Kumari	S. Nandegari
Designation	QC Analyst	Asst. Manager	Sr. Manager

Works: M/s Vasudha Pharma Chem Limited, Unit-III, Plot No:23&24, Jawaharlal Nehru Pharma City, Thanam (V),
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