



Pharmaceuticals Limited

Registered & Corporate Office :

Plot No. 72, H. No. 8-2-334/3 & 4, Road No. 5,  
Opp. SBI Executive Enclave, Banjara Hills,  
Hyderabad - 500 034, Telangana, INDIA.  
Tel : +91-40-2525 9999, Fax : +91-40-2525 9889  
CIN : L24239TG1987PLC008066  
www.smspharma.com

**CERTIFICATE OF ANALYSIS**

Page 1 of 3

Name of the Product	: Itraconazole USP	A.R. No.	: FP/20/0835
Batch No	: ITZ/0120023	Date of Analysis	: 18.01.2021
Quantity	: 48.0 Kg	Expiry Date	: December - 2025
Mfg. Date	: January - 2021		

S. No.	Test parameter	Result	Specifications (Ref. No.:CS-FP-5043-03,Rev.05)
1.	Description	White powder.	A White or almost white powder.
2.	Solubility	Freely soluble in Methylene chloride, Sparingly soluble in Tetrahydrofuran, very slightly soluble in Alcohol, practically insoluble in water.	Freely soluble in Methylene chloride, Sparingly soluble in Tetrahydrofuran, very slightly soluble in Alcohol, practically insoluble in water.
3.	Identification		
	a. by IR	The IR absorption spectrum of the sample is match with the spectrum of the Itraconazole working standard.	The IR absorption spectrum of the sample should match with the spectrum of the Itraconazole Reference standard / working standard.
	b. by HPLC	The Retention time of the major peak of the sample solution is corresponds to that of the standard solution, as obtained in the assay.	The Retention time of the major peak of the sample solution should be corresponds to that of the standard solution, as obtained in the assay.
4.	Optical rotation $[\alpha]_D^{20}$ measured at 20°C	+ 0.03	Between - 0.10° and + 0.10°
5.	Loss on drying at 105°C for 4 hours (% w/w)	0.21	Not more than 0.5
6.	Residue on ignition (% w/w)	0.04	Not more than 0.1

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Naga Bhushan Reddy	J. Naresh Babu	V. Satya Kiran
Designation	Executive - QA	Dy. Manager - QC	Sr. Executive- QA

Works : Unit-II, Plot No. 24 & 24B and 36 & 37, S.V. Co-Operative Industrial Estate, Bachupally,  
Medchal-Malkajgiri District, Hyderabad, Telangana - 500 090, INDIA. Phone : +91 91000 72351 / 52  
Email : qa\_unit2@smspharma.com, Website : www.smspharma.com



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7.	Organic impurities by HPLC (% w/w)		
	4-methoxy derivative	BDL (0.05)	Not more than 0.2
	4-Triazolyl isomer	0.12	Not more than 0.3
	Sum of Propyl analog & Isopropyl analog	0.06	Not more than 0.3
	Epimer	BDL (0.05)	Not more than 0.2
	n-Butyl isomer	BDL (0.05)	Not more than 0.2
	Didioxolanyl analog	0.08	Not more than 0.3
	Any unspecified impurity	BDL (0.05)	Not more than 0.10
	Total impurities	0.25	Not more than 0.8
8.	Assay by HPLC on dried basis (% w/w)	100.1	Not less than 98.0 and Not more than 102.0
9.	Residual Solvents by GC (ppm)		
	Methanol	Below LOD (14)	Not more than 300
	Acetone	Below LOD (21)	Not more than 500
	Toluene	321	Not more than 890
	N,N-Dimethyl formamide	Below LOD (53)	Not more than 440
	Dimethyl sulfoxide	Below LOD (55)	Not more than 500

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Sign & Date			
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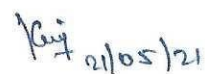
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<b>* Additional tests</b>			
10.	Particle size distribution by Malvern (Dry method)		
	D(0.1)	1.3	Not more than 5 µm
	D(0.5)	5.8	Not more than 10 µm
	D(0.9)	15.8	Not more than 25 µm
11.	Identification of polymorph by XRPD	XRPD diffractogram exhibit specific 2θ value at 10.7, 14.4, 16.6, 17.5, 17.9, 19.4, 20.4, 21.2, 23.5, 25.3, 25.5 and 27.1.	XRPD diffractogram should exhibit specific 2θ value at ± 0.2° of 10.8, 14.5, 16.6, 17.5, 18.0, 19.4, 20.4, 21.2, 23.5, 25.3, 25.5 and 27.1.

Conclusion: -The product conforms to the **Itraconazole USP** Specifications.

BDL: - Below Disregard Limit, LOD: - Limit of Detection, LOQ :- Limit of Quantitation

	Prepared by	Reviewed by	Approved by
Sign & Date	 21/05/21	 21/05/21	 21/05/21
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