

12/07/2023

CERTIFICATE OF ANALYSIS

Name of the Product : Itraconazole Ph. Eur.	
Batch No : ITZ/0922014	
Mfg. Quantity : 47.8 Kg	A.R. No. : FP/22/0445
Dispatch Quantity : 5 Kg	Date of Analysis : 13.10.2022
Mfg. Date : September – 2022	Expiry Date : August – 2027

S. No.	TEST PARAMETER	RESULT	SPECIFICATIONS (Ref. No.: CS-FP-5043-02,Rev.01)
1.	Characters		
	a) Appearance	White powder.	White or almost white powder.
	b) Solubility	Practically insoluble in water, freely soluble in methylene chloride, very slightly soluble in ethanol (96 percent).	Practically insoluble in water, freely soluble in methylene chloride, very slightly soluble in ethanol (96 percent).
2.	Identification 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 working standard.
3.	Appearance of solution	10%, w/v solution in methylene chloride is clear and not more intensely coloured than reference solution B ₆	10%, w/v solution in methylene chloride should be clear and not more intensely coloured than reference solution R ₆ or B ₆
4.	Related Substances by HPLC (%)		
	Impurity B	0.08	Not more than 0.3
	Impurity G	Below LOQ (0.021)	Not more than 0.3
	Impurity E	Below LOD (0.006)	Not more than 0.2
	Sum of impurities C and D	0.08	Not more than 0.3
	Un specified impurity	0.03	Not more than 0.10
	Total impurities	0.27	Not more than 0.8

	Prepared by	Reviewed by	Approved by
Sign & Date	<i>12/06/23</i>	<i>12/06/23</i>	<i>12/06/23</i>
Name	G. Vara Kumar	J. Naresh Babu	M. Yedukondalu
Designation	Chemist – QA	Dy. Manager – QC	Asst. Manager – QA



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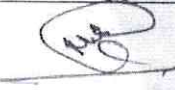
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5.	Loss on drying at 105°C for 4 hours (%w/w)	0.21	Not more than 0.5
6.	Sulphated ash (%w/w)	0.03	Not more than 0.1
7.	Assay on dried basis by Potentiometry (%w/w)	100.2	Not less than 99.0 and Not more than 101.0
8.	Residual Solvents by GC (ppm)		
	Methanol	Below LOQ (47)	Not more than 3000
	Acetone	Below LOD (21)	Not more than 5000
	N,N-Dimethyl formamide	Below LOD (53)	Not more than 880
	Toluene	296	Not more than 890
	Dimethyl sulfoxide	Below LOD (55)	Not more than 5000

Conclusion: The product conforms to the **Itraconazole Ph. Eur.** Specifications.

LOD: Limit of Detection

	Prepared by	Reviewed by	Approved by
Sign & Date	 12/06/23	 12/06/23	 12/06/23
Name	G. Vara Kumar	J. Naresh Babu	M. Yedukondalu
Designation	Chemist – QA	Dy. Manager – QC	Asst. Manager – QA

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