



pharmaceuticals ltd.

Regd. & Corporate Office :

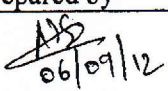
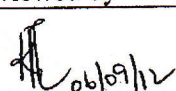
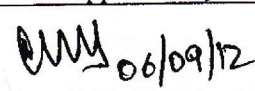
Plot No. 19-111, Road No. 71,
Opp. Bharatiya Vidya Bhavan Public School,
Jubilee Hills, Hyderabad - 500 034, A.P., INDIA
Tel : +91-40-6628 8888, Fax : +91-40-2355 1401/402

CERTIFICATE OF ANALYSIS

Page 1 of 2

Name of the Product	: Itraconazole Ph.Eur.		
Batch No	: ITZ/1111004	A.R. No.	: FP/11/0145
Mfg.Quantity	: 22.5 Kg	Date of Analysis	: 16.11.2011
Mfg. Date	: November - 2011	Retest Date	: October - 2013

S. No.	Test parameter	Result	Specifications
1.	Characters	White powder.	White or almost white powder.
	a) Appearance		
	b) Solubility	Practically insoluble in water, freely soluble in methylene chloride, very slightly soluble in ethanol	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 concordant with that of 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 (%)		
	a) Impurity B	0.10	Not more than 0.3
	b) Impurity G	BDL	Not more than 0.3
	c) Impurity E	BDL	Not more than 0.2
	d) Sum of impurities C and D	0.10	Not more than 0.3
	e) Un specified impurity	BDL	Not more than 0.10
	f) Total impurities	0.20	Not more than 0.8
5.	Loss on drying at 105°C for 4 hours (%w/w)	0.3	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)	100.1	Not less than 99.0 and Not more than 101.0

	Prepared by	Reviewed by	Approved by
Sign & Date	 06/09/12	 06/09/12	 06/09/12
Name	N.Satya Krishna	M.Lakshminipathi Rao	N.V.V.Satyanarayana
Designation	Executive - QA	Manager - QC	Sr.Manager - QA



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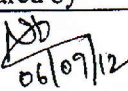
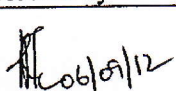
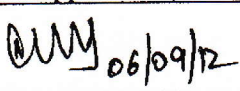
Name of the Product	: Itraconazole Ph.Eur.		
Batch No	: ITZ/1111004	A.R. No.	: FP/11/0145
Mfg.Quantity	: 22.5 Kg	Date of Analysis	: 16.11.2011
Mfg. Date	: November - 2011	Retest Date	: October - 2013

S. No.	Test parameter	Result	Specifications
8.	Residual Solvents (by GC) (ppm)		
	a) Methanol	Below LOD(1.5)	Not more than 3000
	b) Acetone	Below LOD(0.7)	Not more than 5000
	c) N,N-Dimethyl formamide	Below LOD(26.4)	Not more than 880
	d) Toluene	166	Not more than 890
	e) Dimethyl sulfoxide	Below LOD(70.4)	Not more than 5000

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

BDL: Below disregarding level (0.05) %.

LOD: Limit of detection

	Prepared by	Reviewed by	Approved by
Sign & Date	 06/07/12	 06/09/12	 06/09/12
Name	N.Satya Krishna	M.Lakshmi pathi Rao	N.V.V.Satyanarayana
Designation	Executive - QA	Manager - QC	Sr.Manager - QA