

# Kalchem International

## Chemicals & Compounding Supplies

### CERTIFICATE OF ANALYSIS

Product Name : ITRACONAZOLE		Reference : EP	
Batch No. : IT0160514		Mfg. Date : MAY 2014	
Batch Quantity : 5.00 kg		Retest Date : APRIL 2017	
A.R Number : ITP-0080/14		Date of Analysis: 30.05.2014	
Sl.No	TESTS	SPECIFICATIONS	RESULTS
1.0	Description	A white or almost white powder.	A white powder
2.0	Solubility	Practically insoluble in water, freely soluble in Methylene chloride, sparingly soluble in Tetrahydrofuran, very slightly soluble in alcohol.	Complies
3.0	Identification by IR	The Infra Red absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wavelengths as that of a similar preparation of Itraconazole Working Standard.	Complies
4.0	Appearance of solution	A solution of 2 g in 20ml Methylene chloride should be clear and not more intensely coloured than BY <sub>6</sub> .	Complies
5.0	Optical rotation	-0.10 <sup>0</sup> to +0.10 <sup>0</sup>	+0.01 <sup>0</sup>
6.0	Related Substances by HPLC		
	Maximum Single Impurity	Not more than 0.5%	0.10%
	Total Impurities	Not more than 1.25%	0.39%
7.0	Loss on drying	Not more than 0.5% w/w	0.24%
8.0	Sulphated Ash	Not more than 0.1% w/w	0.08%
9.0	Assay on dried basis	Not less than 98.5% and not more than 101.5% w/w	100.1%
<b>Note:</b> The product <b>Conforms</b> to the above specifications.			
Prepared by : <i>ME</i>		Checked by : <i>BSS/1114</i>	Authorized by : <i>[Signature]</i>
Date: <i>30/05/14</i>		Date: <i>30/05/14</i>	Date : <i>30/05/14</i>

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