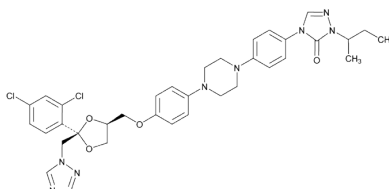




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CERTIFICATE OF ANALYSIS

ITRACONAZOLE USP MICRONIZED



Molecular Formula: C₃₅H₃₈Cl₂N₈O₄
 Molecular Weight: 705.63g/mol

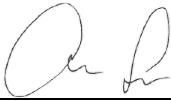
Lot No. 17022003170302
CAS # 84625-61-6
Storage Condition Room Temperature

Manufacture Date 01/2016
Expiration Date 12/2020
Country of Origin India

TEST	SPECIFICATION	RESULT
Description	White or almost White powder	Complies
Solubility	Freely soluble in Methylene Chloride. Sparingly soluble in Tetrahydrofuran. Very slightly soluble in Alcohol. Practically insoluble in Water.	Complies
Identification (IR)	Complies with USP specification	Complies
Identification (HPLC)	Complies with USP specification	Complies
Optical Rotation	(-0.1 °) - 0.1 °	-0.03 °
Loss on Drying	≤ 0.5 %	0.22 %
Residue on Ignition	≤ 0.1 %	0.005 %
4-Methoxy Derivative	≤ 0.2 %	BDL
4-Trizolyl Isomer	≤ 0.3 %	0.10 %
Sum of Propyl Analog and Isopropyl Analog	≤ 0.3 %	BDL
Epimer	≤ 0.2 %	BDL
n-Butyl Isomer	≤ 0.2 %	BDL
Didioxolanyl Analog	≤ 0.3 %	BDL
Unspecified Impurities	≤ 0.1 %	BDL
Total Impurities	≤ 0.8 %	0.1 %
Assay (Dried)	98.5 - 101.5 %	99.7 %
Methanol	≤ 300 ppm	BDL
Acetone	≤ 500 ppm	BDL
N, N-Dimethyl Formamide	≤ 440 ppm	BDL
Toluene	≤ 890 ppm	182 ppm
Dimethyl Sulfoxide	≤ 500 ppm	BDL



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Quality Signature	
Compendium	USP 40
Date	03/02/2017
Conclusion	APPROVED