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Piramal

QAD-F-3002-01

CERTIFICATE OF ANALYSIS

PRODUCT	**: KETOCONAZOLE**	**COMPENDIA**	**: USP-42**
BATCH No	**: KET/M-35220**	**BATCH QUANTITY**	**: 268.50 Kg**
MFG. DATE	**: AUGUST.2020**	**EXP. DATE**	**: JULY.2025**
APPROVED ON	**: 23/11/20**	**DISPATCH QUANTITY**	**: 268.34 Kg**
QC. A.R.No.: FP/304/2020			

TESTS	RESULTS	SPECIFICATIONS
1. DESCRIPTION	Almost white powder.	A White or almost white powder.
2. SOLUBILITY	Practically insoluble in water, Freely soluble in dichloromethane, soluble in Methanol, Sparingly soluble in ethanol (96%).	Practically insoluble in water, Freely soluble in dichloromethane, soluble in Methanol, sparingly soluble in ethanol (96%).
3. IDENTIFICATION		
a) IR Absorption	Sample spectrum concordant with that of working standard.	IR Absorption spectrum of the sample is concordant with that of Ketoconazole USP Reference Standard/Working Standard.
b) HPLC	Sample retention time matched with Standard retention time	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
4. SPECIFIC ROTATION	0°	Between -1° and +1°
5. LOSS ON DRYING	0.2%	Not more than 0.5% w/w
6. RESIDUE ON IGNITION	0.0%	Not more than 0.1% w/w
7. ORGANIC IMPURITIES BY HPLC		
i) Individual Unspecified impurity	Not Quantified	Not more than 0.10%
ii) Total impurities	Not Quantified	Not more than 0.50%
8. ASSAY (BY HPLC) (On the dried basis)	100.2%	Not less than 98.0%w/w and Not more than102.0%w/w of $C_{26}H_{28}Cl_2N_4O_4$
9. RESIDUAL SOLVENTS (BY GC-HS)		
CLASS -2. Residual Solvents		
a) Methanol	128 ppm	Not more than 500 ppm
b) Methylene chloride	0 ppm	Not more than 100 ppm

REMARKS: The above product conforms to **USP-42** Specifications.

Prepared by Sign & Date	Checked by Sign & Date	Approved by Sign & Date
25/11/20	25/11/20	25/11/20
Executive-QC	**Executive-QC**	**Manager-QC**

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