

**QUALITY CONTROL
CERTIFICATE OF ANALYSIS**

DO/2168

PRODUCT NAME : KETOCONAZOLE EP	
CAS NO. : 65277-42-1	QUANTITY : 50.0 Kgs.
BATCH NO. : KET / 11401031	DATE OF ANALYSIS : 01/02/2014
MFG. DATE : JAN. - 2014	DATE OF RELEASE : 01/02/2014
EXP. DATE : DEC. - 2018	QC A. R. NO. : KET / 01 / 0031

SR. NO.	TESTS	RESULTS	LIMITS
1	a. Appearance	Almost White Powder.	White to almost White Powder.
	b. Solubility	Practically insoluble in Water, Freely soluble in Methylene Chloride, Soluble in Methanol, Sparingly soluble in ethanol (96%).	Practically insoluble in Water, Freely soluble in Methylene Chloride, Soluble in Methanol, Sparingly soluble in ethanol (96%).
2	Identification by		
	a. Melting Point	148.8°C – 150.4°C	Between 148.0° to 152.0°C
	b. IR Spectrum	The Infrared absorption spectrum of Sample concordant with Infrared absorption spectrum of Ketoconazole WS.	The Infrared absorption spectrum of Sample concordant with Infrared absorption spectrum of Ketoconazole WS.
	c. TLC	The Principal spot in the chromatogram obtained with the test solution is similar in position, colour & size to the principle spot in the chromatogram obtained with the reference solution (a).	The Principal spot in the chromatogram obtained with the test solution is similar in position, colour & size to the principle spot in the chromatogram obtained with the reference solution (a).
	d. Reaction of Chloride	Complies	The solution gives reaction (a) of chlorides.
3	Appearance of solution	Solution is Clear and not more intensely coloured than Reference Solution BY4	Solution S should be Clear and not more intensely coloured than Reference Solution BY4.
4	Optical Rotation	(+) 0.000°	- 0.10° to + 0.10° determined on solution S
5	Related Substances	0.12 %	Total Impurity NMT 0.5 %
6	Heavy Metals	Less than 20 ppm	Maximum 20 ppm
7	Loss on Drying	0.26 %	Maximum 0.5% determined on 1g by drying in an oven at 105°C
8	Sulphated Ash	0.06 %	Maximum 0.10 % determined on 1g
9	Assay by Potentiometer (On Dried Basis)	100.0 %	NLT 99.0 % and NMT 101.0 % calculated with reference to the dried substance.
10	Residual solvent ➤ Methanol ➤ Ethyl Acetate ➤ Acetone	235.83 ppm Nil 427.91 ppm	Not More Than 3000 ppm Not More Than 5000 ppm Not More Than 5000 ppm

Remark – The above material Complies as per EP 7 specifications.

Prepared by	Checked by	Approved by
<i>Aditya</i> 07/02/2014	<i>CB</i> 07/02/2014	<i>Korh</i> 05/02/2014

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