



# Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

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## QUALITY CONTROL CERTIFICATE OF ANALYSIS

PRODUCT NAME	: KETOCONAZOLE EP	BATCH SIZE	: 450.0 Kg.
BATCH NO.	: KET / 11506209	A. R. No.	: FP/KET/15/0093
MFG. DATE	: JUN.- 2015	ANALYSIS DATE	: 09 / 07 / 2015
EXP. DATE	: MAY- 2020	CAS No.	: 65277-42-1

SR. NO.	TESTS	SPECIFICATION	RESULTS
1	a. Appearance	White to almost White Powder.	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	Between 148.0° to 152.0°C	148.1°C – 149.1°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	The solution gives reaction (a) of chlorides.	Complies
3	Appearance of solution	Solution S should be Clear and not more intensely coloured than Reference Solution BY <sub>4</sub> .	Solution is Clear and not more intensely coloured than Reference Solution BY <sub>4</sub> .
4	Optical Rotation	- 0.10° to + 0.10° determined on solution S	(-) 0.005°
5	Related Substances	Total Impurity NMT 0.5 %	0.09 %
6	Heavy Metals	Maximum 20 ppm	Less than 20 ppm
7	Loss on Drying	Maximum 0.5% determined on 1g by drying in an oven at 105°C	0.27 %
8	Sulphated Ash	Maximum 0.10 % determined on 1g	0.06 %
9	Assay by Potentiometer (On Dried Basis)	NLT 99.0 % and NMT 101.0 % calculated with reference to the dried substance.	99.86 %
10*	Residual solvent		
	> Methanol > Acetone	Not More Than 3000 ppm Not More Than 5000 ppm	234.85 ppm 484.76 ppm

Remark – The above material Complies as per EP 8 specifications.

\*Additional Tests as per party requirement.

Prepared by	Checked by	Approved by
QC Officer <i>[Signature]</i> 26/09/2015	QC Officer / Executive <i>[Signature]</i> Date 26/09/2015	QC Head <i>[Signature]</i> 26/09/2015
Date	Date	Date

Manufacturing Site : Plot No. E-21, MIDC, Tarapur, Tal. & Dist. - Palghar - 401 506, (MH), INDIA  
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