



# Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

**CORPORATE OFFICE :** Plot No. 109-D, Mahendra Industrial Estate, Ground Floor, Road No. 29, Sion (East), Mumbai - 400 022 (MH) India.  
Tel.: +91 22 2407 2249 / 2401 9025  
Email: sales@aartidrugs.com • expert@aartidrugs.com  
Website: www.aartidrugs.com  
CIN No.: L37060MH1984PLC055433  
**Manufacturing Site :** Plot No. E-21, M.I.D.C., Tarapur, Tal. & Dist. Palghar - 401 506, Maharashtra, India.  
Tel.: +91 2525 - 275841 / 260550  
Email : adle21@aartidrugs.com

## QUALITY CONTROL CERTIFICATE OF ANALYSIS

PRODUCT NAME	: KETOCONAZOLE EP	BATCH SIZE	: 500.00 Kg.
BATCH NO.	: KET / 124040204	A. R. No.	: FG / 24 / 0465
MFG. DATE	: APR - 2024	ANALYSIS DATE	: 04 / 05 / 2024
EXP. DATE	: MAR - 2029	CAS No.	: 65277-42-1

SR. NO.	TESTS	SPECIFICATION	RESULTS
1.	Appearance	White to almost White Powder.	Almost White Powder.
2.	Solubility	Practically insoluble in Water. Freely soluble in Methylene Chloride. Soluble in Methanol. Sparingly soluble in ethanol (96 percent).	Practically insoluble in Water. Freely soluble in Methylene Chloride. Soluble in Methanol. Sparingly soluble in ethanol (96 percent).
3.	Identification		
	A. 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.
	B. Melting Point	Result A : 148.0° to 152.0°C Result B : The absolute difference between the melting point of the mixture and the value obtained in determination A is not greater than 2°C	150.1 °C 0.2°C
4.	Appearance of solution	Solution S should be Clear and not more intensely coloured than Reference Solution BY4 (Method II)	Solution is Clear and not more intensely coloured than Reference Solution BY4.
5.	Optical Rotation	- 0.10° to + 0.10° determined on solution S	(+) 0.003 °
6.	Related Substances By HPLC	Impurity D: Maximum 0.2 percent. Unspecified Impurities : for each impurity, Maximum 0.10 percent Total Impurity : Not More Than 0.3 percent.	0.102 % 0.071 % 0.196 %
7.	Loss on Drying	Maximum 0.5 percent determined on 1g by drying in an oven at 105°C.	0.22 %
8.	Sulfated Ash	Maximum 0.1 percent determined on 1g.	0.048 %
9.	Assay by (On Dried Basis)	99.0 percent to 101.0 percent	100.15 %

**Remark** – The above material Complies as per EP 11.4 specifications.

Prepared by	Checked by	Approved by
QC Officer ( Mrs. S. N. Patil ) <i>[Signature]</i>	QC Executive ( Mr. D. L. Zope ) <i>[Signature]</i>	QC Head ( Mr. S. K. Pawar ) <i>[Signature]</i>
Date <i>07/05/2024</i>	Date <i>07/05/2024</i>	Date <i>07/05/2024</i>

**METAPHARMACEUTICAL**

N° DE LOTE:

**0080624**

*[Signature]* 12/06/2024