

METAPHARMACEUTICAL

N DE LOTE:

0070925

QUALITY CONTROL CERTIFICATE OF ANALYSIS

Agarwal
01/09/2025

PRODUCT NAME	: KETOCONAZOLE EP	BATCH SIZE	: 500.00 Kg
BATCH NO.	: KET / 125070380	A.R.No.	: FG / 25 / 0785
MFG.DATE	: Jul - 2025	ANALYSIS DATE	: 17 / 07 / 2025
EXP.DATE	: Jun - 2030	CAS No.	: 65277-42-1

SR. NO.	TESTS	SPECIFICATION	RESULTS
1	Appearance	White or 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 %).	Practically insoluble in water. Freely soluble in methylene chloride. Soluble in methanol. Sparingly soluble in ethanol (96 %).
3	Identification		
	A. By IR	The infrared absorption spectrum of sample should be concordant with infrared absorption spectrum of Ketoconazole WS.	The infrared absorption spectrum of sample is concordant with infrared absorption spectrum of Ketoconazole WS.
	B. Melting Point	Result A : 148.0°C 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 .	149.7°C 0.4°C
4	Appearance of Solution	Solution S should be clear and not more intensely coloured than Reference Solution BY4 .	Solution S is clear and not more intensely coloured than Reference Solution BY4 .
5	Optical Rotation	- 0.10° to + 0.10° determined on solution S	(-) 0.001°
6	Related Substances (By HPLC)	Impurity D: Maximum 0.2 %	0.081%
		Unspecified impurities : For each impurity Maximum 0.10 %	0.048%
		Total Impurity : Maximum 0.3 %	0.217%
7	Loss on Drying	Maximum 0.5 % determined on 1.000 g by drying in an oven at 105°C	0.19%
8	Sulfated Ash	Maximum 0.1 % determined on 1.0 g .	0.052%
9	Assay (On Dried Basis)	99.0 % to 101.0 %	100.21%

Remark : The above material Complies as per EP 11.4 Specification.

Prepared By	Checked By	Approved By
QC Officer (Miss. P. J. Bhoir)	QC Executive (Mr. D. B. Kadam)	QC Head (Mr. S. K. Pawar)
Date <i>P. Bhoir</i> 17/07/2025	Date <i>D. B. Kadam</i> 17/07/2025	Date <i>S. K. Pawar</i> 17/07/2025