Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

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QUALITY CONTROL
CERTIFICATE OF ANALYSIS

PRODUCT NAME : KETOCONAZOLE EP		BATCH SIZE	: 515.00 Kg.
BATCH NO. : KET / 123120663		A. R. No.	: FP/KET/23/0728
MFG. DATE : DEC - 2023		ANALYSIS DATE	: 26 / 12 / 2023
EXP. DATE : NOV - 2028		CAS No.	: 65277-42-1

SR. NO.	TESTS	SPECIFICATION	RESULTS
1.	Characters		
	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 percent).	Practically insoluble in Water. Freely soluble in Methylene Chloride. Soluble in Methanol. Sparingly soluble in ethanol (96 percent).
2.	Identification		
	A. Melting Point	148.0° to 152.0°C	150.1 °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. Thin Layer Chromatography	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 BY4 (Method II)	Solution is Clear and not more intensely coloured than Reference Solution BY_4.
4.	Optical Rotation	– 0.10° to + 0.10° determined on solution S	(-) 0.000 °
5.	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.	0.048 % 0.074 % 0.198 %
6.	Loss on Drying	Maximum 0.5 percent determined on 1g by drying in an oven at 105°C .	0.20 %
7.	Sulfated Ash	Maximum 0.1 percent determined on 1g .	0.051 %
8.	Assay by (On Dried Basis)	99.0 percent to 101.0 percent	100.17 %

Remark – The above material Complies as per EP 11.0 specifications.

Prepared by	Checked by	Approved by
QC Officer (Mrs. S. N. Patil)	QC Executive (Mr. D. B. Kadam)	QC Head (Mr. S. K .Pawar)
Date 26/12/2023	Date 26/12/2023	Date 26/12/2023

METAPHARMACEUTICAL

N DE LOTE:
0040224

05/02/2024