

Lot - 0010120



Aarti Drugs Limited

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**QUALITY CONTROL
CERTIFICATE OF ANALYSIS**

| PRODUCT NAME : KETOCONAZOLE EP | | BATCH SIZE : 425.00 Kg. | |
|--------------------------------|------------------------------|--|--|
| BATCH NO. : KET / 11909401 | | A. R. No. : FP/KET/19/0438 | |
| MFG. DATE : SEP - 2019 | | ANALYSIS DATE : 09 / 10 / 2019 | |
| EXP. DATE : AUG - 2024 | | 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 | 150.0°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. 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 BY4. |
| 4. | Optical Rotation | - 0.10° to + 0.10° determined on solution S | (+) 0.003° |
| 5. | Related Substances By HPLC | Total Impurity : Not More Than 0.5 percent. | 0.113 % |
| 6. | Loss on Drying | Maximum 0.5 percent determined on 1g by drying in an oven at 105°C. | 0.23 % |
| 7. | Sulfated Ash | Maximum 0.1 percent determined on 1g. | 0.054 % |
| 8. | Assay by (On Dried Basis) | 99.0 percent to 101.0 percent | 100.45 % |
| 9* | Residual solvent | | |
| | > Methanol > Acetone | Not More Than 3000 ppm Not More Than 5000 ppm | 157.18 ppm 559.67 ppm |

Remark - The above material Complies as per EP 9 specifications.

*Additional Tests as per party requirement.

| Prepared by | Checked by | Approved by |
|-----------------------------|-----------------------------------|---------------------------|
| QC Officer (Mr. D. L. Zope) | QC Executive (Mr. S. R. Kosarkar) | QC Head (Mr. S. K. Pawar) |
| Date 05/12/2019 | Date 05/12/2019 | Date 05/12/2019 |