



# Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

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## QUALITY CONTROL CERTIFICATE OF ANALYSIS

|              |                                      |               |                  |
|--------------|--------------------------------------|---------------|------------------|
| PRODUCT NAME | : KETOCONAZOLE USP<br>( Micronised ) | BATCH SIZE    | : 500.00 Kg      |
| BATCH NO.    | : KET / 125040184                    | A.R.No.       | : FG / 25 / 0374 |
| MFG.DATE     | : Apr - 2025                         | ANALYSIS DATE | : 14 / 04 / 2025 |
| EXP.DATE     | : Mar - 2030                         | CAS No.       | : 65277-42-1     |

| SR. NO. | TESTS                         | SPECIFICATION                                                                                                                           | RESULTS                                                                                                                                 |
|---------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| 1*      | Description                   | White to off white powder.                                                                                                              | Off white powder.                                                                                                                       |
| 2*      | Solubility                    | Practically insoluble in water.<br>Freely soluble in methylene chloride.<br>Soluble in Methanol.<br>Sparingly soluble in Ethanol (96%). | Practically insoluble in water.<br>Freely soluble in methylene chloride.<br>Soluble in Methanol.<br>Sparingly soluble in Ethanol (96%). |
| 3       | Identification                |                                                                                                                                         |                                                                                                                                         |
|         | A. By IR                      | Sample spectra should be concordant with Infrared absorption spectrum of Ketoconazole USP WS.                                           | Sample spectra is concordant with Infrared absorption spectrum of Ketoconazole USP WS.                                                  |
|         | B. By HPLC                    | The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay.      | The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.     |
| 4       | Specific Rotation             | - 1° to + 1°                                                                                                                            | (+) 0.024°                                                                                                                              |
| 5       | Loss on drying                | NMT 0.5%                                                                                                                                | 0.19%                                                                                                                                   |
| 6       | Residue on ignition           | NMT 0.1%                                                                                                                                | 0.048%                                                                                                                                  |
| 7       | Assay                         | NLT 98.0% and NMT 102.0% ,<br>calculated on the dried basis.                                                                            | 100.92%                                                                                                                                 |
| 8       | Organic Impurities<br>by HPLC | i) unspecified impurity : NMT 0.10%                                                                                                     | 0.073%                                                                                                                                  |
|         |                               | ii) Total Impurities : NMT 2.0%                                                                                                         | 0.274%                                                                                                                                  |
| 9**     | Particle Size                 | 90 % < 10 microns<br>99 % < 25 microns                                                                                                  | 90 % = 5.67 microns<br>99.38 % = 9.86 microns                                                                                           |

**Remark :** The above material Complies as per USP 2024 Specification.

\* Inhouse Test. \*\* Additional test as per party requirement.

| Prepared By                                                               | Checked By                                                                | Approved By                                                          |
|---------------------------------------------------------------------------|---------------------------------------------------------------------------|----------------------------------------------------------------------|
| QC Officer ( Miss. P. J. Bhoir )<br><i>P. J. Bhoir</i><br>Date 17/04/2025 | QC Executive ( Mr. D. B. Kadam )<br><i>D. B. Kadam</i><br>Date 17/04/2025 | QC Head ( Mr. S. K. Pawar )<br><i>S. K. Pawar</i><br>Date 17/04/2025 |