



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 220437**

|                   |   |
|-------------------|---|
| Product:          | KETOCONAZOLE  |
| Lot:              | 220437  |
| Expiry date:      | 01/07/2026  |
| Reference:        | Cumple PhEur10.6  |
| Synonyms:         |   |
| Formula:          | C <sub>26</sub> H <sub>28</sub> Cl <sub>2</sub> N <sub>4</sub> O <sub>4</sub> |
| Molecular weight: | 531,4 g/mol   |

| Assay   | Result      | Specification   |   |
|---|-------------|-----------------|---|
| Identification  | Conform (B) | Test PhEur (A)  |   |
| Organoleptic properties                                       | Conform     | PhEur           |   |
| Appearance of 10% solution (CH <sub>2</sub> Cl <sub>2</sub> ) | Conform     | PhEur           |   |
| Optical rotation  | 0,0         | (-0,1) - (+0,1) |   |
| Related substances (HPLC)                                     | Conform     |                 |   |
| Loss on drying  | 0,09 %      | <= 0,5 %        |   |
| Sulphated ashes   | 0,00 %      | <= 0,1%         |   |
| ASSAY (anhydrous vehicle PFP)                                 | 100,0 %     | 99,0-101,0%     |   |
| Elemental impurities  | Conform     | Test PhEur      | # |
| Impurity D  | 0,13 %      | <= 0,2 %        |   |
| Unspecified Impurities  | 0,08 %      | <= 0,10 %       |   |
| Total impurities  | 0,21 %      | <= 0,3 %        |   |
| Residual solvent: Methanol                                    | <=3000 ppm  | <= 3000 ppm     | # |
| Residual solvent: acetone                                     | <=5000 ppm  | <= 5000 ppm     | # |

Organoleptic characteristics: White or almost white powder. Practically insoluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96 per cent).

Conservation: In airtight containers. Protect from light. Readily oxidable.

Date of analysis: 23/02/2022

Judgement:  
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00001 AARTI DRUGS LTD.

Manufacturer batch: KET-12108345

| Product | Name                   | Capacity | Batch      |
|---------|------------------------|----------|------------|
| 1155191 | KETOCONAZOL (INACTIVO) | 1 g      | 220437-D-1 |
| 1155191 | KETOCONAZOL (INACTIVO) | 1 g      | 220437-D-2 |
| 1155192 | KETOCONAZOL            | 5 g      | 220437-E-1 |

|         |                   |       |            |
|---------|-------------------|-------|------------|
| 1155192 | KETOCONAZOL       | 5 g   | 220437-E-2 |
| 1155193 | KETOCONAZOL       | 10 g  | 220437-F-2 |
| 1155194 | KETOCONAZOL       | 25 g  | 220437-G-1 |
| 1155194 | KETOCONAZOL       | 25 g  | 220437-G-2 |
| 1155196 | KETOCONAZOL       | 100 g | 220437-J-2 |
| 1155196 | KETOCONAZOL       | 100 g | 220437-J-3 |
| 1200184 | KETOCONAZOL       | 1 kg  | 220437-P-1 |
| 1200186 | KETOCONAZOL       | 250 g | 220437-N-1 |
| 1200186 | KETOCONAZOL       | 250 g | 220437-N-2 |
| 1370117 | KETOCONAZOL (FLB) | 100 g | 220437-J-1 |
| 1370128 | KETOCONAZOL (FLB) | 10 g  | 220437-F-1 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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