



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 222494

| | |
|--------------------|---|
| Product: | KETOCONAZOLE |
| Lot: | 222494 |
| Expiry date: | 31/07/2026 |
| Reference: | Cumple PhEur10.7 |
| Synonyms: | |
| Formule: | C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄ |
| Poids moléculaire: | 531,4 g/mol |

| Assay | Result | Specification | |
|---|-------------|-----------------|---|
| Identification | Conform (B) | Test PhEur (A) | |
| Organoleptic properties | Conform | PhEur | |
| Appearance of 10% solution (CH ₂ Cl ₂) | Conform | PhEur | |
| Optical rotation | 0,0 | (-0,1) - (+0,1) | |
| Related substances (HPLC) | Conform | | |
| Loss on drying | 0,12 % | <= 0,5 % | |
| Sulphated ashes | 0,00 % | <= 0,1% | |
| ASSAY (anhydrous vehicle PFP) | 99,8 % | 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: 28/04/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00001 AARTI DRUGS LTD.

Manufacturer batch: KET-12108345

| Produit | Nom | Capacité | Lot |
|---------|------------------------|----------|------------|
| 1155191 | KETOCONAZOL (INACTIVO) | 1 g | 222494-D-1 |
| 1155192 | KETOCONAZOL | 5 g | 222494-E-1 |
| 1155192 | KETOCONAZOL | 5 g | 222494-E-2 |

| | | | |
|---------|-------------------|-------|------------|
| 1155193 | KETOCONAZOL | 10 g | 222494-F-1 |
| 1155193 | KETOCONAZOL | 10 g | 222494-F-2 |
| 1155196 | KETOCONAZOL | 100 g | 222494-J-2 |
| 1200184 | KETOCONAZOL | 1 kg | 222494-P-1 |
| 1200184 | KETOCONAZOL | 1 kg | 222494-P-2 |
| 1200186 | KETOCONAZOL | 250 g | 222494-N-1 |
| 1200186 | KETOCONAZOL | 250 g | 222494-N-2 |
| 1370117 | KETOCONAZOL (FLB) | 100 g | 222494-J-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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