



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233161

| | |
|--------------------|---|
| Product: | ITRACONAZOLE |
| Lot: | 233161 |
| Expiry date: | 30/06/2028 |
| Reference: | Cumple PhEur11.2 |
| Synonyms: | |
| Formule: | C ₃₅ H ₃₈ Cl ₂ N ₈ O ₄ |
| Poids moléculaire: | 706 g/mol |

| Assay | Result | Specification | |
|-----------------------------------|------------|----------------|---|
| Identification | Conform | | |
| Organoleptic properties | Conform | PhEur | |
| Appearance of solution | Conform | | |
| Related substances (HPLC) | Conform | | |
| Loss on drying | 0,03 % | <= 0,5 % | |
| Sulphated ashes | 0,00 % | <= 0,1 % | |
| Assay | 99,6 % | 99,0 - 101,0 % | |
| Elemental impurities | Conform | Test PhEur | # |
| Impurity B | 0,08 % | <= 0,3 % | |
| Impurity E | < 0,05 % | <= 0,2 % | |
| Impurity G | < 0,05 % | <= 0,3 % | |
| Sum of impurities C and D | < 0,05 % | <= 0,3 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Total impurities | 0,08 % | <= 0,8 % | |
| Residual solvent: Tetrahydrofuran | < 720 ppm | <= 720 ppm | # |
| Residual solvent: Methanol | < 3000 ppm | <= 3000 ppm | # |

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 20/07/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00393 QUÍMICA SINTÉTICA, S.A.

Manufacturer batch: KD0A3319

| | | | |
|---------|-------------|----------|------------|
| Produit | Nom | Capacité | Lot |
| 1100122 | ITRACONAZOL | 10 g | 233161-F-1 |

| | | | |
|---------|-------------|-------|------------|
| 1100122 | ITRACONAZOL | 10 g | 233161-F-3 |
| 1100122 | ITRACONAZOL | 10 g | 233161-F-4 |
| 1100122 | ITRACONAZOL | 10 g | 233161-F-5 |
| 1100124 | ITRACONAZOL | 100 g | 233161-J-1 |
| 1100124 | ITRACONAZOL | 100 g | 233161-J-2 |
| 1100124 | ITRACONAZOL | 100 g | 233161-J-3 |
| 1100124 | ITRACONAZOL | 100 g | 233161-J-4 |
| 1100125 | ITRACONAZOL | 250 g | 233161-N-1 |
| 1100127 | ITRACONAZOL | 1 kg | 233161-P-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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