



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 212403

| | |
|--------------------|------------------|
| Product: | FINASTERIDE |
| Lot: | 212403 |
| Expiry date: | 07/08/2025 |
| Reference: | Cumple PhEur10.4 |
| Synonyms: | Finasteride. |
| Formule: | C23H36N2O2 |
| Poids moléculaire: | 372,55 g/mol |

| Assay | Result | Specification | |
|--------------------------------------|-------------|-------------------|---|
| Loss on drying | 0,06 % | <=0,5% | |
| Residual solvent: Isopropyl acetate | <= 5000 ppm | <= 5000 ppm | # |
| Assay (HPLC) | 99,7 % | 98,0 - 102,0 % | |
| Residual solvent: Ethanol | <= 5000 ppm | <= 5000 ppm | # |
| Specific rotation | +13,1 | (+12,0) - (+14,0) | |
| Residual solvent: methylene chloride | <= 600 ppm | <= 600 ppm | # |
| Related substances (HPLC) | Conform | | |
| Residual solvent: Toluene | <= 890 ppm | <= 890 ppm | # |
| Identification | Conform | Test PhEur | |
| Total impurities | 0,13 % | <= 0,5 % | |
| Organoleptic properties | Conform | PhEur | |
| Residual solvent: Methanol | <= 3000 ppm | <= 3000 ppm | # |
| Impurity C | 0,13 % | <= 0,3 % | |
| Unspecified Impurities | <= 0,05 % | <= 0,10 % | |
| Elemental impurities | Conform | Test PhEur | # |
| Impurity A | <= 0,05 % | <= 0,3 % | |

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect form light and moisture.

Date of analysis: 18/05/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: EU-FTD200802M

| Produit | Nom | Capacité | Lot |
|---------|-------------|----------|------------|
| 1144981 | FINASTERIDA | 1 g | 212403-D-1 |
| 1144981 | FINASTERIDA | 1 g | 212403-D-2 |

| | | | |
|---------|-------------|-------|------------|
| 1144982 | FINASTERIDA | 5 g | 212403-E-1 |
| 1144982 | FINASTERIDA | 5 g | 212403-E-2 |
| 1144982 | FINASTERIDA | 5 g | 212403-E-3 |
| 1144983 | FINASTERIDA | 10 g | 212403-F-1 |
| 1144983 | FINASTERIDA | 10 g | 212403-F-2 |
| 1144983 | FINASTERIDA | 10 g | 212403-F-3 |
| 1144984 | FINASTERIDA | 25 g | 212403-G-1 |
| 1144985 | FINASTERIDA | 100 g | 212403-J-1 |
| 1144985 | FINASTERIDA | 100 g | 212403-J-2 |
| 1144986 | FINASTERIDA | 250 g | 212403-N-1 |
| 1144986 | FINASTERIDA | 250 g | 212403-N-2 |

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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