



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 215061**

|                    |                  |
|--------------------|------------------|
| Product:           | FINASTERIDE      |
| Lot:               | 215061           |
| Expiry date:       | 15/05/2026       |
| Reference:         | Cumple PhEur10.5 |
| Synonyms:          | Finasteride.     |
| Formule:           | C23H36N2O2       |
| Poids moléculaire: | 372,55 g/mol     |

| Assay                                | Result      | Specification     |   |
|--------------------------------------|-------------|-------------------|---|
| Assay (HPLC)                         | 98,8 %      | 98,0 - 102,0 %    |   |
| Residual solvent: Ethanol            | <= 5000 ppm | <= 5000 ppm       | # |
| Related substances (HPLC)            | Conform     |                   |   |
| Residual solvent: Toluene            | <= 890 ppm  | <= 890 ppm        | # |
| Loss on drying                       | 0,16 %      | <=0,5%            |   |
| Residual solvent: Isopropyl acetate  | <= 5000 ppm | <= 5000 ppm       | # |
| Organoleptic properties              | Conform     | PhEur             |   |
| Residual solvent: Methanol           | <= 3000 ppm | <= 3000 ppm       | # |
| Specific rotation                    | +13,0       | (+12,0) - (+14,0) |   |
| Residual solvent: methylene chloride | <= 600 ppm  | <= 600 ppm        | # |
| Unspecified Impurities               | 0,05 %      | <= 0,10 %         |   |
| Identification                       | Conform     | Test PhEur        |   |
| Total impurities                     | 0,44 %      | <= 0,5 %          |   |
| Impurity A                           | 0,27 %      | <= 0,3 %          |   |
| Impurity C                           | 0,12 %      | <= 0,3 %          |   |
| Elemental impurities                 | Conform     | Test PhEur        | # |

Organoleptic characteristics:

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

Date of analysis: 08/10/2021

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: EU-FTD210502M

| Produit | Nom         | Capacité | Lot        |
|---------|-------------|----------|------------|
| 1144981 | FINASTERIDA | 1 g      | 215061-D-1 |
| 1144981 | FINASTERIDA | 1 g      | 215061-D-2 |

|         |             |       |            |
|---------|-------------|-------|------------|
| 1144981 | FINASTERIDA | 1 g   | 215061-D-3 |
| 1144981 | FINASTERIDA | 1 g   | 215061-D-4 |
| 1144982 | FINASTERIDA | 5 g   | 215061-E-1 |
| 1144982 | FINASTERIDA | 5 g   | 215061-E-2 |
| 1144982 | FINASTERIDA | 5 g   | 215061-E-3 |
| 1144983 | FINASTERIDA | 10 g  | 215061-F-1 |
| 1144983 | FINASTERIDA | 10 g  | 215061-F-2 |
| 1144984 | FINASTERIDA | 25 g  | 215061-G-1 |
| 1144984 | FINASTERIDA | 25 g  | 215061-G-2 |
| 1144984 | FINASTERIDA | 25 g  | 215061-G-3 |
| 1144985 | FINASTERIDA | 100 g | 215061-J-1 |
| 1144985 | FINASTERIDA | 100 g | 215061-J-2 |
| 1144985 | FINASTERIDA | 100 g | 215061-J-3 |
| 1144986 | FINASTERIDA | 250 g | 215061-N-1 |
| 1144986 | FINASTERIDA | 250 g | 215061-N-2 |
| 1144986 | FINASTERIDA | 250 g | 215061-N-3 |

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

ACOFARMA DISTRIBUCIÓN, S.A.  
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)  
Tel./ 93-736.00.88

[www.acofarma.com](http://www.acofarma.com)

Date d'édition: 06/01/2025

