



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 227033**

|                    |  |
|--------------------|--|
| Product:           | FLUTAMIDE  |
| Lot:               | 227033   |
| Expiry date:       | 30/11/2027   |
| Reference:         | Cumple PhEur11.0   |
| Synonyms:          |  |
| Formule:           | C <sub>11</sub> H <sub>11</sub> F <sub>3</sub> N <sub>2</sub> O <sub>3</sub> |
| Poids moléculaire: | 276,22 g/mol   |

| Assay                     | Result     | Specification  |   |
|---------------------------|------------|----------------|---|
| Identification            | Conform    |                |   |
| Organoleptic properties   | Conform    |                |   |
| Melting point             | 113 °C     | Approx. 112 °C |   |
| Elemental impurities      | Conform    | Test PhEur     | # |
| Related substances (HPLC) | Conform    |                | = |
| Loss on drying            | 0,03 %     | <= 0,5%        |   |
| Sulphated ashes           | 0,06 %     | <= 0,1%        | = |
| Assay (HPLC)              | 99,3 %     | 97,5- 102,0 %  |   |
| Impurity A                | 0,03 %     | <= 0,2 %       | = |
| Impurity B                | ND         | <= 0,2 %       | = |
| Impurity C                | 0,01 %     | <= 0,2 %       | = |
| Unspecified Impurities    | ND         | <= 0,10 %      | = |
| Total impurities          | 0,04 %     | <= 0,5 %       | = |
| Residual solvent: Ethanol | < 5000 ppm | <= 5000 ppm    | # |
| Residual solvent: Toluene | < 890 ppm  | <= 890 ppm     | # |

Organoleptic characteristics: Light yellow, crystalline powder. Practic. insoluble in water, freely soluble in acetone and in ethanol 96%, practic. insoluble in heptane.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 03/02/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00394 DERIVADOS QUÍMICOS, S.A.U.

Manufacturer batch: 670002R03N

| Produit | Nom       | Capacité | Lot        |
|---------|-----------|----------|------------|
| 1145226 | FLUTAMIDA | 5 g      | 227033-E-2 |
| 1145226 | FLUTAMIDA | 5 g      | 227033-E-4 |

|         |                 |       |            |
|---------|-----------------|-------|------------|
| 1145226 | FLUTAMIDA       | 5 g   | 227033-E-5 |
| 1145226 | FLUTAMIDA       | 5 g   | 227033-E-7 |
| 1145227 | FLUTAMIDA       | 25 g  | 227033-G-1 |
| 1145228 | FLUTAMIDA       | 100 g | 227033-J-1 |
| 1145228 | FLUTAMIDA       | 100 g | 227033-J-2 |
| 1145228 | FLUTAMIDA       | 100 g | 227033-J-3 |
| 1145228 | FLUTAMIDA       | 100 g | 227033-J-4 |
| 1145228 | FLUTAMIDA       | 100 g | 227033-J-5 |
| 1145231 | FLUTAMIDA       | 1 kg  | 227033-P-1 |
| 1145231 | FLUTAMIDA       | 1 kg  | 227033-P-2 |
| 1145231 | FLUTAMIDA       | 1 kg  | 227033-P-3 |
| 1145231 | FLUTAMIDA       | 1 kg  | 227033-P-4 |
| 1370215 | FLUTAMIDA (FLB) | 5 g   | 227033-E-1 |
| 1370215 | FLUTAMIDA (FLB) | 5 g   | 227033-E-3 |
| 1370215 | FLUTAMIDA (FLB) | 5 g   | 227033-E-6 |

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'édición: 20/05/2026

