



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 240837**

|                   |                                                                             |
|-------------------|-----------------------------------------------------------------------------|
| Product:          | FAMOTIDINE                                                                  |
| Lot:              | 240837                                                                      |
| Expiry date:      | 15/11/2026                                                                  |
| Reference:        | Cumple PhEur11.4                                                            |
| Synonyms:         |                                                                             |
| Formula:          | C <sub>8</sub> H <sub>15</sub> N <sub>7</sub> O <sub>2</sub> S <sub>3</sub> |
| Molecular weight: | 337,43 g/mol                                                                |

| Assay                         | Result     | Specification |   |
|-------------------------------|------------|---------------|---|
| Impurity B                    | 0,06 %     | <= 0,15 %     |   |
| Impurity C                    | < 0,05 %   | <= 0,3 %      |   |
| Impurity A                    | < 0,05 %   | <= 0,15 %     |   |
| Appearance of solution        | Conform    |               |   |
| Impurity G                    | < 0,05 %   | <= 0,15 %     |   |
| Elemental impurities          | Conform    |               | # |
| Unspecified Impurities        | 0,06 %     | <= 0,10 %     |   |
| Identification                | Conform    | Test PhEur    |   |
| Impurity D                    | < 0,05 %   | <= 0,3 %      |   |
| Organoleptic properties       | Conform    |               |   |
| Impurity F                    | < 0,05 %   | <= 0,15 %     |   |
| Sulphated ashes               | 0,01 %     | <= 0,1%       |   |
| Residual solvent: acetone     | < 5000 ppm | <= 5000 ppm   | # |
| Assay (on anhydrous)          | 99,5 %     | 98,5-101,5%   |   |
| Residual solvent: Isopropanol | < 5000 ppm | <= 5000 ppm   | # |
| Related substances (HPLC)     | Conform    |               |   |
| Total impurities              | 0,12 %     | <= 0,8 %      |   |
| Loss on drying                | 0,09 %     | <= 0,5 %      |   |
| Residual solvent: Methanol    | < 3000 ppm | <= 3000 ppm   | # |

Organoleptic characteristics: White or yellowish-white, crystalline powder or crystals. Very slightly sol. in water, freely solub. in glacial acetic acid, very slightly sol. in anhydrous EtOH, pract. insol. in ethyl acetate. It dissolves in dil. mineral ac.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/05/2024

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01003 ERCROS, S.A.

Judgement:  
APPROVED

Manufacturer batch: F 483

| Product | Name       | Capacity | Batch      |
|---------|------------|----------|------------|
| 1144063 | FAMOTIDINA | 5 g      | 240837-E-1 |
| 1144063 | FAMOTIDINA | 5 g      | 240837-E-2 |
| 1144066 | FAMOTIDINA | 50 g     | 240837-I-1 |
| 1144066 | FAMOTIDINA | 50 g     | 240837-I-2 |
| 1144066 | FAMOTIDINA | 50 g     | 240837-I-3 |
| 1144070 | FAMOTIDINA | 1 Kg     | 240837-P-1 |
| 1144070 | FAMOTIDINA | 1 Kg     | 240837-P-2 |
| 1144070 | FAMOTIDINA | 1 Kg     | 240837-P-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

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