



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252119

| | |
|-------------------|--|
| Product: | CIMETIDINE |
| Lot: | 252119 |
| Expiry date: | 30/10/2030 |
| Reference: | Cumple PhEur11.8 |
| Synonyms: | |
| Formula: | C ₁₀ H ₁₆ N ₆ S |
| Molecular weight: | 252,34 g/mol |

| Assay | Result | Specification | |
|-------------------------------|-------------|----------------|---|
| Identification | Conform (B) | Test PhEur (B) | |
| Organoleptic properties | Conform | PhEur | |
| Appearance of solution | Conform | | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Loss on drying | 0,01% | <= 0,5 % | |
| Sulphated ashes | 0,08% | <= 0,2% | |
| Assay | 99,5 % | 98,5 - 101,5 % | |
| Impurity B | < 0,05 % | <= 0,2 % | |
| Impurity C | ND | <= 0,2 % | |
| Impurity D | ND | <= 0,2 % | |
| Impurity E | < 0,05 % | <= 0,2 % | |
| Impurity F | < 0,05 % | <= 0,2 % | |
| Impurity G | < 0,05 % | <= 0,2 % | |
| Impurity H | < 0,05 % | <= 0,2 % | |
| Unspecified Impurities | 0,07% | <= 0,10 % | |
| Total impurities | 0,07% | <= 1,0 % | |
| Residual solvent: Ethanol | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: acetone | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Isopropanol | < 5000 ppm | <= 5000 ppm | # |
| Elemental impurities | Conform | | # |
| Nitrosamine impurities | Conform | | # |

Organoleptic characteristics: White or almost white powder. Slightly soluble in water, soluble in ethanol (96 per cent), practically insoluble in methylene chloride. It dissolves in dilute mineral acids. It shows polymorphism.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 16/12/2025

Responsible: B.Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00287 UNION QUIMICO FARMACEUTICA, SA

Manufacturer batch: 2000027501

| Product | Name | Capacity | Batch |
|---------|------------|----------|------------|
| 1119064 | CIMETIDINA | 10 g | 252119-F-1 |
| 1119064 | CIMETIDINA | 10 g | 252119-F-2 |
| 1119065 | CIMETIDINA | 25 g | 252119-G-1 |
| 1119065 | CIMETIDINA | 25 g | 252119-G-2 |
| 1119067 | CIMETIDINA | 100 g | 252119-J-1 |
| 1119067 | CIMETIDINA | 100 g | 252119-J-2 |
| 1200116 | CIMETIDINA | 1 kg | 252119-P-1 |
| 1200116 | CIMETIDINA | 1 kg | 252119-P-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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