



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 211878

| | |
|-------------------|-------------------------------------------------------------------------------|
| Product: | CETIRIZINE DIHYDROCHLORIDE |
| Lot: | 211878 |
| Expiry date: | 01/07/2025 |
| Reference: | Cumple PhEur10.4 |
| Synonyms: | Cetirizina hidrocloruro. |
| Formula: | C ₂₁ H ₂₇ Cl ₃ N ₂ O ₃ |
| Molecular weight: | 461,8 g/mol |

| Assay | Result | Specification | |
|---------------------------|---------------|----------------|---|
| Sulphated ashes | 0,00 % | <= 0,2 % | |
| Loss on drying | 0,14 % | <= 0,5 % | |
| Residual solvent: acetone | <= 5000 ppm | <= 5000 ppm | # |
| Elemental impurities | Conform | Test PhEur | # |
| Assay | 100,6 % | 99,0 - 101,0 % | |
| Impurity B | <= 0,05 % | <= 0,15 % | |
| Impurity A | <= 0,05 % | <= 0,15 % | |
| Identification | Conform (B,D) | | |
| Impurity D | NDT | <= 0,15 % | |
| Impurity C | NDT | <= 0,15 % | |
| Appearance of solution | Conform | Test PhEur | |
| Impurity F | <= 0,05 % | <= 0,15 % | |
| Organoleptic properties | Conform | Test PhEur | |
| Impurity E | <= 0,05 % | <= 0,15 % | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Total impurities | <= 0,3 % | <= 0,3 % | |
| pH of solution S | 1,4 | 1,2 - 1,8 | |
| Unspecified Impurities | <= 0,05 % | <= 0,10 % | |

Organoleptic characteristics: White or almost white powder, freely soluble in water, practically insoluble in acetone and in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 14/04/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00026 IPCA LABORATORIES LIMITED

Manufacturer batch: 20025CZ6RII

| Product | Name | Capacity | Batch |
|---------|--------------------------------------------|----------|------------|
| 1000680 | CETIRIZINA DIHIDROCLORURO | 5 g | 211878-E-4 |
| 1000680 | CETIRIZINA DIHIDROCLORURO | 5 g | 211878-E-5 |
| 1000680 | CETIRIZINA DIHIDROCLORURO | 5 g | 211878-E-6 |
| 1000680 | CETIRIZINA DIHIDROCLORURO | 5 g | 211878-E-7 |
| 1000681 | CETIRIZINA DIHIDROCLORURO | 25 g | 211878-G-1 |
| 1000681 | CETIRIZINA DIHIDROCLORURO | 25 g | 211878-G-2 |
| 1000681 | CETIRIZINA DIHIDROCLORURO | 25 g | 211878-G-3 |
| 1000681 | CETIRIZINA DIHIDROCLORURO | 25 g | 211878-G-4 |
| 1000683 | CETIRIZINA DIHIDROCLORURO | 100 g | 211878-J-1 |
| 1000683 | CETIRIZINA DIHIDROCLORURO | 100 g | 211878-J-2 |
| 1370140 | CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO) | 10 g | 211878-F-1 |
| 1370140 | CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO) | 10 g | 211878-F-2 |
| 1370140 | CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO) | 10 g | 211878-F-3 |
| 1370140 | CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO) | 10 g | 211878-F-4 |
| 1370140 | CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO) | 10 g | 211878-F-5 |
| 1370140 | CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO) | 10 g | 211878-F-6 |
| 1370141 | CETIRIZINA DIHIDROCLORURO (FLB) | 5 g | 211878-E-1 |
| 1370141 | CETIRIZINA DIHIDROCLORURO (FLB) | 5 g | 211878-E-2 |
| 1370141 | CETIRIZINA DIHIDROCLORURO (FLB) | 5 g | 211878-E-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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