



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250211

Product:	CETIRIZINE DIHYDROCHLORIDE
Lot:	250211
Expiry date:	30/09/2029
Reference:	Cumple PhEur11.6
Synonyms:	Cetirizina hidrocloruro.
Formula:	C ₂₁ H ₂₇ Cl ₃ N ₂ O ₃
Molecular weight:	461,8 g/mol

Assay	Result	Specification	
Identification	Conform (B,D)		
Organoleptic properties	Conform	Test PhEur	
Appearance of solution	Conform	Test PhEur	
pH of solution S	1,6	1,2 - 1,8	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,09 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,2 %	
Assay	100,6 %	99,0 - 101,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	< 0,05 %	<= 0,15 %	
Impurity B	0,07 %	<= 0,15 %	
Impurity C	< 0,05 %	<= 0,15 %	
Impurity D	ND	<= 0,15 %	
Impurity E	< 0,05 %	<= 0,15 %	
Impurity F	0,08 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,15 %	<= 0,3 %	
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#

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: 06/02/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00026 IPCA LABORATORIES LIMITED

Manufacturer batch: 24061CZ6RII

Product	Name	Capacity	Batch
1000680	CETIRIZINA DIHIDROCLORURO	5 g	250211-E-2
1000680	CETIRIZINA DIHIDROCLORURO	5 g	250211-E-4
1000680	CETIRIZINA DIHIDROCLORURO	5 g	250211-E-5
1000681	CETIRIZINA DIHIDROCLORURO	25 g	250211-G-1
1000681	CETIRIZINA DIHIDROCLORURO	25 g	250211-G-2
1000683	CETIRIZINA DIHIDROCLORURO	100 g	250211-J-1
1000683	CETIRIZINA DIHIDROCLORURO	100 g	250211-J-2
1000683	CETIRIZINA DIHIDROCLORURO	100 g	250211-J-3
1370141	CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO)	5 g	250211-E-1
1370141	CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO)	5 g	250211-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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Date of edition: 22/04/2026

