



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224625

Product:	CETIRIZINE DIHYDROCHLORIDE
Lot:	224625
Expiry date:	31/03/2026
Reference:	Cumple PhEur10.8
Synonyms:	Cetirizina hidrocloreuro.
Formula:	C ₂₁ H ₂₇ Cl ₃ N ₂ O ₃
Molecular weight:	461,8 g/mol

Assay	Result	Specification	
Appearance of solution	Conform	Test PhEur	
Impurity F	NDT	<= 0,15 %	
Organoleptic properties	Conform	Test PhEur	
Impurity E	< 0,05 %	<= 0,15 %	
Identification	Conform (B,D)		
Impurity D	NDT	<= 0,15 %	
Impurity C	NDT	<= 0,15 %	
Impurity B	< 0,05 %	<= 0,15 %	
Impurity A	NDT	<= 0,15 %	
Elemental impurities	Conform	Test PhEur	#
Assay	99,5 %	99,0 - 101,0 %	
Sulphated ashes	0,00 %	<= 0,2 %	
Loss on drying	0,07 %	<= 0,5 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Related substances (HPLC)	Conform	Test PhEur	
Total impurities	< 0,05 %	<= 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: 02/09/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00026 IPCA LABORATORIES LIMITED

Manufacturer batch: 21015CZ6RII

Product	Name	Capacity	Batch
1000680	CETIRIZINA DIHIDROCLORURO	5 g	224625-E-1
1000680	CETIRIZINA DIHIDROCLORURO	5 g	224625-E-3
1000681	CETIRIZINA DIHIDROCLORURO	25 g	224625-G-1
1000681	CETIRIZINA DIHIDROCLORURO	25 g	224625-G-4
1000683	CETIRIZINA DIHIDROCLORURO	100 g	224625-J-1
1000683	CETIRIZINA DIHIDROCLORURO	100 g	224625-J-2
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	224625-E-2
1370142	CETIRIZINA DIHIDROCLORURO (FLB)	25 g	224625-G-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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