



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 220397**

Product:	CETIRIZINE DIHYDROCHLORIDE
Lot:	220397
Expiry date:	01/03/2026
Reference:	Cumple PhEur10.6
Synonyms:	Cetirizina hidrocloruro.
Formula:	C <sub>21</sub> H <sub>27</sub> Cl <sub>3</sub> N <sub>2</sub> O <sub>3</sub>
Molecular weight:	461,8 g/mol

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

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: 15/02/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00026 IPCA LABORATORIES LIMITED

Manufacturer batch: 21017CZ6RII

Product	Name	Capacity	Batch
1000680	CETIRIZINA DIHIDROCLORURO	5 g	220397-E-1
1000680	CETIRIZINA DIHIDROCLORURO	5 g	220397-E-4
1000680	CETIRIZINA DIHIDROCLORURO	5 g	220397-E-7
1000681	CETIRIZINA DIHIDROCLORURO	25 g	220397-G-1
1000681	CETIRIZINA DIHIDROCLORURO	25 g	220397-G-2
1000681	CETIRIZINA DIHIDROCLORURO	25 g	220397-G-3
1000683	CETIRIZINA DIHIDROCLORURO	100 g	220397-J-1
1000683	CETIRIZINA DIHIDROCLORURO	100 g	220397-J-2
1370140	CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO)	10 g	220397-F-1
1370140	CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO)	10 g	220397-F-2
1370140	CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO)	10 g	220397-F-3
1370140	CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO)	10 g	220397-F-4
1370140	CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO)	10 g	220397-F-5
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	220397-E-2
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	220397-E-3
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	220397-E-5
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	220397-E-6

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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