



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 231275

Product:	CETIRIZINE DIHYDROCHLORIDE
Lot:	231275
Expiry date:	30/11/2027
Reference:	Cumple PhEur11.0
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	0,01 %	<= 0,2 %	
Assay	100,0 %	99,0 - 101,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity B	< 0,05 %	<= 0,15 %	
Impurity C	ND	<= 0,15 %	
Identification	Conform (B,D)		
Impurity D	ND	<= 0,15 %	
Organoleptic properties	Conform	Test PhEur	
Impurity E	< 0,05 %	<= 0,15 %	
Appearance of solution	Conform	Test PhEur	
Impurity F	ND	<= 0,15 %	
pH of solution S	1,3	1,2 - 1,8	
Unspecified Impurities	0,07 %	<= 0,10 %	
Related substances (HPLC)	Conform	Test PhEur	
Total impurities	0,07 %	<= 0,3 %	
Loss on drying	0,10 %	<= 0,5 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Impurity A	ND	<= 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: 23/03/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00026 IPCA LABORATORIES LIMITED

Manufacturer batch: 22043CZ6RII

Product	Name	Capacity	Batch
1000680	CETIRIZINA DIHIDROCLORURO	5 g	231275-E-1
1000680	CETIRIZINA DIHIDROCLORURO	5 g	231275-E-10
1000680	CETIRIZINA DIHIDROCLORURO	5 g	231275-E-4
1000680	CETIRIZINA DIHIDROCLORURO	5 g	231275-E-5
1000680	CETIRIZINA DIHIDROCLORURO	5 g	231275-E-7
1000680	CETIRIZINA DIHIDROCLORURO	5 g	231275-E-8
1000681	CETIRIZINA DIHIDROCLORURO	25 g	231275-G-1
1000681	CETIRIZINA DIHIDROCLORURO	25 g	231275-G-2
1000681	CETIRIZINA DIHIDROCLORURO	25 g	231275-G-3
1000681	CETIRIZINA DIHIDROCLORURO	25 g	231275-G-5
1000681	CETIRIZINA DIHIDROCLORURO	25 g	231275-G-6
1000683	CETIRIZINA DIHIDROCLORURO	100 g	231275-J-1
1000683	CETIRIZINA DIHIDROCLORURO	100 g	231275-J-2
1000683	CETIRIZINA DIHIDROCLORURO	100 g	231275-J-3
1370140	CETIRIZINA DIHIDROCLORURO (FLB) (INACTIVO)	10 g	231275-F-1
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	231275-E-2
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	231275-E-3
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	231275-E-6
1370141	CETIRIZINA DIHIDROCLORURO (FLB)	5 g	231275-E-9

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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