



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 260762**

Product:	CETIRIZINE DIHYDROCHLORIDE
Lot:	260762
Expiry date:	30/08/2030
Reference:	Cumple PhEur12.2
Synonyms:	Cetirizina hidrocloruro.
Formule:	C <sub>21</sub> H <sub>27</sub> Cl <sub>3</sub> N <sub>2</sub> O <sub>3</sub>
Poids moléculaire:	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	1,5	1,2 - 1,8	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,20 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,2 %	
Assay	100,0 %	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	< 0,05 %	<= 0,15 %	
Impurity E	< 0,05 %	<= 0,15 %	
Impurity F	0,13 %	<= 0,15 %	
Unspecified Impurities	0,09 %	<= 0,10 %	
Total impurities	0,29 %	<= 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: 08/06/2026

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00026 IPCA LABORATORIES LIMITED

Manufacturer batch: 25034CZ6RII

Produit	Nom	Capacité	Lot
1000680	CETIRIZINA DIHIDROCLORURO	5 g	260762-E-1
1000681	CETIRIZINA DIHIDROCLORURO	25 g	260762-G-1

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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