



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252119

Product:	CIMETIDINE
Lot:	252119
Expiry date:	30/10/2030
Reference:	Cumple PhEur11.8
Synonyms:	
Formule:	C ₁₀ H ₁₆ N ₆ S
Poids moléculaire:	252,34 g/mol

Assay	Result	Specification	
Identification	Conform (B)	Test PhEur (B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,01%	<= 0,5 %	
Sulphated ashes	0,08%	<= 0,2%	
Assay	99,5 %	98,5 - 101,5 %	
Impurity B	< 0,05 %	<= 0,2 %	
Impurity C	ND	<= 0,2 %	
Impurity D	ND	<= 0,2 %	
Impurity E	< 0,05 %	<= 0,2 %	
Impurity F	< 0,05 %	<= 0,2 %	
Impurity G	< 0,05 %	<= 0,2 %	
Impurity H	< 0,05 %	<= 0,2 %	
Unspecified Impurities	0,07%	<= 0,10 %	
Total impurities	0,07%	<= 1,0 %	
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform		#
Nitrosamine impurities	Conform		#

Organoleptic characteristics: White or almost white powder. Slightly soluble in water, soluble in ethanol (96 per cent), practically insoluble in methylene chloride. It dissolves in dilute mineral acids. It shows polymorphism.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 16/12/2025

Responsible: B.Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00287 UNION QUIMICO FARMACEUTICA, SA
Manufacturer batch: 2000027501

Produit	Nom	Capacité	Lot
1119064	CIMETIDINA	10 g	252119-F-1
1119064	CIMETIDINA	10 g	252119-F-2
1119065	CIMETIDINA	25 g	252119-G-1
1119065	CIMETIDINA	25 g	252119-G-2
1119067	CIMETIDINA	100 g	252119-J-1
1119067	CIMETIDINA	100 g	252119-J-2
1200116	CIMETIDINA	1 kg	252119-P-1
1200116	CIMETIDINA	1 kg	252119-P-2

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 d'édition: 21/06/2026

