



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250149

Product:	CIMETIDINE
Lot:	250149
Expiry date:	05/11/2029
Reference:	Cumple PhEur11.6
Synonyms:	
Formula:	C10H16N6S
Molecular weight:	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	0,05 %	<= 0,5 %	
Sulphated ashes	0,0 %	<= 0,2%	=
Assay	100,7 %	98,5 - 101,5 %	
Impurity B	< 0,05 %	<= 0,2 %	=
Impurity C	< 0,05 %	<= 0,2 %	=
Impurity D	< 0,05 %	<= 0,2 %	=
Impurity E	< 0,05 %	<= 0,2 %	=
Impurity F	< 0,05 %	<= 0,2 %	=
Impurity G	0,1 %	<= 0,2 %	=
Impurity H	0,1 %	<= 0,2 %	=
Unspecified Impurities	< 0,05 %	<= 0,10 %	=
Total impurities	0,1 %	<= 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: 28/01/2025

Responsible: B. Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00287 UNION QUIMICO FARMACEUTICA, SA

Manufacturer batch: 10402000023801

Product	Name	Capacity	Batch
1119064	CIMETIDINA	10 g	250149-F-2
1119064	CIMETIDINA	10 g	250149-F-4
1119065	CIMETIDINA	25 g	250149-G-1
1119065	CIMETIDINA	25 g	250149-G-2
1119067	CIMETIDINA	100 g	250149-J-2
1119067	CIMETIDINA	100 g	250149-J-4
1200116	CIMETIDINA	1 kg	250149-P-1
1200116	CIMETIDINA	1 kg	250149-P-2
1370108	CIMETIDINA (FLB)	10 g	250149-F-1
1370108	CIMETIDINA (FLB)	10 g	250149-F-3
1370109	CIMETIDINA (FLB)	100 g	250149-J-1
1370109	CIMETIDINA (FLB)	100 g	250149-J-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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