



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 231217

Product:	CIMETIDINE
Lot:	231217
Expiry date:	09/01/2028
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C ₁₀ H ₁₆ N ₆ S
Molecular weight:	252,34 g/mol

Assay	Result	Specification	
Identification	Conform(B)	Test PhEur (B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		=
Heavy metals	< 20 ppm	<= 20 ppm	=
Related substances (HPLC)	Conform	Test PhEur	=
Loss on drying (1 g, 105°C)	0,1 %	<= 0,5%	
Sulphated ashes	< 0,2 %	<= 0,2%	=
ASSAY (anhydrous vehicle PFP)	100,0 %	98,5-101,5%	
Impurity B	< 0,2 %	<= 0,2 %	=
Impurity C	< 0,2 %	<= 0,2 %	=
Impurity D	< 0,2 %	<= 0,2 %	=
Impurity E	< 0,2 %	<= 0,2 %	=
Impurity F	< 0,2 %	<= 0,2 %	=
Impurity G	< 0,2 %	<= 0,2 %	=
Impurity H	< 0,2 %	<= 0,2 %	=
Unspecified Impurities	< 0,10 %	<= 0,10 %	=
Total impurities	< 1,0%	<= 1,0 %	=
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	< 1000 ppm	<= 1000 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#

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: 17/03/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00287 UNION QUIMICO FARMACEUTICA, SA

Manufacturer batch: 10402000018601

Product	Name	Capacity	Batch
1119064	CIMETIDINA	10 g	231217-F-1
1119064	CIMETIDINA	10 g	231217-F-4
1119065	CIMETIDINA	25 g	231217-G-1
1119065	CIMETIDINA	25 g	231217-G-2
1119065	CIMETIDINA	25 g	231217-G-3
1119067	CIMETIDINA	100 g	231217-J-2
1119067	CIMETIDINA	100 g	231217-J-3
1119067	CIMETIDINA	100 g	231217-J-5
1119067	CIMETIDINA	100 g	231217-J-7
1119067	CIMETIDINA	100 g	231217-J-9
1200116	CIMETIDINA	1 kg	231217-P-1
1200116	CIMETIDINA	1 kg	231217-P-2
1200116	CIMETIDINA	1 kg	231217-P-3
1200116	CIMETIDINA	1 kg	231217-P-4
1200116	CIMETIDINA	1 kg	231217-P-5
1370108	CIMETIDINA (FLB)	10 g	231217-F-2
1370108	CIMETIDINA (FLB)	10 g	231217-F-3
1370109	CIMETIDINA (FLB)	100 g	231217-J-1
1370109	CIMETIDINA (FLB)	100 g	231217-J-4
1370109	CIMETIDINA (FLB)	100 g	231217-J-6
1370109	CIMETIDINA (FLB)	100 g	231217-J-8

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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