Unión Químico Farmacéutica, S.A.
Mallorca 262 - 08008 Barcelona , España
Telf: 934879477 - Fax: 934879477
E-mail: uquifa@uquifa.com
VAT: ESA08036774

Certificate of Analysis

Date of issue: 18/10/2024

Product Data

Product name: CIMETIDINA
Product code: 1040

Batch data

Batch number: 10402000022701 Manufacturing date: 19/09/2024 Retest date: 18/09/2029
Analysis: 890000006211

Specification	Result	Specification range	Unit	Method
Appearance	Complies	White or almost white powder		Appearance
Identification B (IR)	Positive	The spectrum of the major peak of the sample corresponds to that of the standard solution as obtained in Assay.		Identification by IR
Loss on drying	0.0	Max. 0.5	%	Loss on drying
Appearance of Solution	Complies	Must be clear and not more intensely coloured than Y5		Appearance of Solution
Sulphated Ash	0.0	Max. 0.2	%	Sulphated Ash
Assay (Titration)	99.4	98.5 - 101.5	%	Assay (Titration)
Impurity B	<0.05	Max. 0.2	%	Related Substances (HPLC)
Impurity C	<0.05	Max. 0.10	%	Related Substances (HPLC)
Impurity D	<0.05	Max. 0.10	%	Related Substances (HPLC)
Impurity E	<0.05	Max. 0.2	%	Related Substances (HPLC)
Impurity F	<0.05	Max. 0.2	%	Related Substances (HPLC)
Impurity G	0.1	Max. 0.2	%	Related Substances (HPLC)
Impurity H	<0.05	Max. 0.2	%	Related Substances (HPLC)
Any other impurity	0.05	Max. 0.10	%	Related Substances (HPLC)
Total impurities	0.1	Max. 1.0	%	Related Substances (HPLC)
Acetone	<3	Max. 1000	ppm	Residual Solvents (GC)
Ethanol	1950	Max. 5000	ppm	Residual Solvents (GC)
Isopropyl alcohol	99	Max. 500	ppm	Residual Solvents (GC)

METAPHARMACEUTICAL
N DE LOTE:
025102U 25/10/2024

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Complies Current Eur. Ph Specification

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7)

Manufacturing Site:
Unión Químico Farmacéutica, S.A.
Polígono Industrial Molí de les Planes, c/Font de Bocs, s/n, C-35 Km 57
08470 Sant Celoni (Barcelona) Spain.

Date of release: 18/10/2024

QC Technician		QA Specialist	
ANGEL NIEVAS		LAIA DE LA VIUDA	
16/10/2024	9:49	18/10/2024	10:59

This is a representation of an electronic record, electronically signed by names and functions shown above. "Dates in CoA defined as DD/MM/YYYY: Day/Month/Year"