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Unión Químico Farmacéutica, S.A.
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Certificate of Analysis

Emission date: 19/02/2021

Product Data

Product name: CIMETIDINE
 Product code: 1040

Batch data

Batch number: 10402000005101 Manufacturing date: 19/01/2021 Retest date: 18/01/2026
 Analysis: 890000001480

Specification	Result	Specification range	Unit	Method
Appearance	Complies	White or almost white powder		Appearance
Identification B (IR)	Positive	Spectrum conforms with the reference standard spectrum		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)	100.0	98.5 - 101.5	%	Assay (Titration)
Impurity B	<0.1	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	<0.1	Max. 0.2	%	Related Substances (HPLC)
Impurity F	<0.1	Max. 0.2	%	Related Substances (HPLC)
Impurity G	0.1	Max. 0.2	%	Related Substances (HPLC)
Impurity H	0.1	Max. 0.2	%	Related Substances (HPLC)
Any other impurity	<0.05	Max. 0.10	%	Related Substances (HPLC)
Total impurities	0.2	Max. 1.0	%	Related Substances (HPLC)
Acetone	<1	Max. 1000	ppm	Residual Solvents
Ethanol	2106	Max. 5000	ppm	Residual Solvents
Isopropyl alcohol	33	Max. 500	ppm	Residual Solvents

Complies Current Eur. Ph Specification



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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.

P.I. Molí de les Planes, C/ Font de Bocs s/n, C-35, Km57 - 08470 Sant Celoni (Barcelona) Spain.

Date of release: 18/02/2021

QC Technician	QA Specialist
SILVIA RODRIGUEZ	LAIA DE LA VIUDA

This is a representation of an electronic record, electronically signed by names and functions shown above.