

Unión Químico Farmacéutica, S.A.
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Certificate of Analysis

Emission date: 29/04/2021

Product Data

Product name: CIMETIDINE
Product code: 1040

Batch data

Batch number: 1040200008201 Manufacturing date: 23/04/2021 Retest date: 22/04/2026
Analysis: 890000002031

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	0.1	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	0.1	Max. 0.2	%	Sulphated Ash
Assay (Titration)	99.6	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	<0.05	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	0.0	Max. 1.0	%	Related Substances (HPLC)
Acetone	<1	Max. 1000	ppm	Residual Solvents
Ethanol	2091	Max. 5000	ppm	Residual Solvents
Isopropyl alcohol	<12	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: 29/04/2021

QC Technician	QA Specialist
CRISTINA TURON	LAIA DE LA VIUDA

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