

COE ACCORDING: 191297
HUU (26/11/19)



Unión Químico Farmacéutica S.A.U.
Mallorca, 262
08008 Barcelona, Spain
+34 934 674 810
+34 934 880 491
uquifa.com

QUALITY CONTROL LABORATORY

CERTIFICATE OF ANALYSIS

CIMETIDINE

Batch No: 10401920024 Manufacturing date: 08/08/2019
Certificate number: 53312 Retest date: August-2024

TEST	REQUIREMENTS	RESULTS
Description	White powder	Complies
Identification IR	Passes test	Passes test
Appearance of solution	Must be clear and not more coloured than Y5	Complies
Loss on drying	max. 0,5%	0,1 %
Sulphated ash	max. 0.2%	0,1 %
Assay	98,5-101,5%	99,8 %
RESIDUAL SOLVENTS:		
Ethyl alcohol	max. 5000ppm	1500ppm
Acetone	max. 1000ppm	<3 ppm
Isopropyl alcohol	max. 500ppm	17 ppm

There is no potential for class 1 solvents to be present and that the material, if tested, will comply with the established standards.

Complies Eur. Ph. 9.4th Edition

MANUFACTURING SITE:

UNION QUIMICO FARMACEUTICA S.A.

Polig. Ind. Molí de les Planes, C/ Font de Bocs s/nº C-35 Km 57, 08470 - Sant Celoni (Barcelona) Spain

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline

Volume 4 Part II (ICH Q7)

DATE OF RELEASE: 29/08/2019

APPROVED

Página 1 de 2

02 OCT. 2019
QC Technician



Registro Mercantil de Barcelona H.19.240 - F.68, T.309 Libro de Sociedades INS.1º - CIF A-09.036774 - Sociedad Unipersonal

COTE ASCEPARMA: J91297
HMO (26/11/19)



Union Quimico Farmaceutica S.A.U.
Mallorca, 262
08008 Barcelona, Spain
+34 934 674 810
+34 934 880 491
uquifa.com

QUALITY CONTROL LABORATORY

CERTIFICATE OF ANALYSIS

CIMETIDINE

Batch No: 10401920024

Manufacturing date: 08/08/2019

Certificate number: 53312

Retest date: August-2024

TEST	REQUIREMENTS	RESULTS
RELATED SUBSTANCES (HPLC):		
Impurity B	max. 0,2%	<0,05 %
Impurity C	max. 0,10%	<0,05 %
Impurity D	max. 0,10%	<0,05 %
Impurity E	max. 0,2%	<0,05 %
Impurity F	max. 0,2%	<0,05 %
Impurity G	max. 0,2%	<0,05 %
Impurity H	max. 0,2%	<0,05 %
Any other impurity	max. 0,10%	0,10 %
Total impurities	max. 1,0%	0,2 %

Complies Eur. Ph. 9.4th Edition

MANUFACTURING SITE:

UNION QUIMICO FARMACEUTICA S.A.

Polig. Ind. Molí de les Planes, C/ Font de Bocs s/nº C-35 Km 57, 08470 - Sant Celoni (Barcelona) Spain

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline

Volume 4 Part II (ICH Q7)

DATE OF RELEASE: 29/08/2019

APPROVED

Página 2 de 2

02 OCT. 2019
QC Technician



Registro Mercantil de Barcelona H 19 240 - F 66, T 309, Libro de Sociedades INS 1º - CIF A-09-035774 - Sociedad Unipersonal