

QUALITY CONTROL LABORATORY
CERTIFICATE OF ANALYSIS

CIMETIDINE

Batch No: 10401620026

Manufacturing date: 27/06/2016

Certificate number: 46621

Retest date: June - 2021

<u>TEST</u>	<u>REQUIREMENTS</u>	<u>RESULTS</u>
Description	White powder	Complies
Identification IR	Passes test	Passes test
Melting Range	139-144°C	141-142 °C
Appearance of solution	Must be clear and not more coloured than Y5	Complies
Loss on drying	max. 0,5%	0,03 %
Heavy metals	max 20ppm	< 20ppm
Sulphated ash	max. 0.2%	0,07 %
Assay	98,5-101,5%	100,4 %

RESIDUAL SOLVENTS:

Ethyl alcohol	max. 5000ppm	2174ppm
Acetone	max. 1000ppm	<1 ppm
Isopropyl alcohol	max. 500ppm	28 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. 8th 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: 21/07/2016

APPROVED

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Quality Control Manager
S. Coto

QA.Responsible
M. Borrás

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RELATED SUBSTANCES (HPLC):		
Impurity B	max. 0,2%	0,01 %
Impurity C	max. 0,10%	<0,01 %
Impurity D	max. 0,10%	0,01 %
Impurity E	max. 0,2%	0,02 %
Impurity F	max. 0,2%	0,04 %
Impurity G	max. 0,2%	0,05 %
Impurity H	max. 0,2%	0,04 %
Any other impurity	max. 0,10%	0,02 %
Total impurities	max. 1,0%	0,38 %

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