Unión Químico Farmacéutica S.A.U.
Mallorca, 262
08008 Barcelona, Spain
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uquifa.com

QUALITY CONTROL LABORATORY

CERTIFICATE OF ANALYSIS

CIMETIDINE

Batch No:	10401620026	**Manufacturing date:**	27/06/2016
Certificate number:	46621	**Retest date:**	June - 2021

TEST	REQUIREMENTS	RESULTS
Description	White powder	Complies
Identification IR	Passes test	Passes test
Melting Range	139-144ºC	141-142 ºC
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 stablished 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 acordance with EU GMP Guideline Volume 4 Part II (ICH Q7)

DATE OF RELEASE: 21/07/2016 APPROVED

Quality Control Manager S. Coto

QA.Responsible M. Borrás

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TEST	**REQUIREMENTS**	**RESULTS**
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 %

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
16L09-1104
Director Técnico

Complies Eur. Ph. 8th Edition

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