Lote SCOFARMS: 170091

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QUALITY CONTROL LABORATORY

CERTIFICATE OF ANALYSIS

RANITIDINE HYDROCHLORIDE (Form II)

Batch No: 12001618006 **Manufacturing date:** 04 / 11 / 2016

Analysis number: 50639 **Retest date:** November - 2019

TEST	REQUIREMENTS	RESULTS
Appearance	White or pale yellow, crystalline powder	Complies
Identification A (IR)	Same bands as the reference standard	Positive
Identification B (Cl)	Qualitative test	Positive
Appearance of solution	Clear and not more intensely coloured than BY5	Complies
pH (1% Water)	4.5 to 6.0	5.4
Loss on drying	Maximum 0.75%	0.02%
Sulfated ash	Maximum 0.1%	0.03%
Heavy metals	Maximum 20 ppm	Complies
Assay	98.5% to 101.5% (on dried substance)	99.8%

Complies Eur. Ph. 8.7th Edition

MANUFACTURING SITE:
UNION QUIMICO FARMACEUTICA, S.A.U.
Polígon Industrial El Pla, Avda. Puigcerdà nº9, C-17, Km 17.4, 08185 LLIÇÀ DE VALL (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: 30 / November / 2016 APPROVED

p.o.

QC Manager
Anna Molina

QA Plant Responsible
Manuel Ron

Responsible Care

NOTE ACEPTADA: 170091

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TEST	REQUIREMENTS		RESULTS
Related substances (HPLC)	Impurity A	: Not more than 0.5%	0.03 %
	Impurity B	: Not more than 0.2%	<0.01 %
	Impurity C	: Not more than 0.2%	<0.01 %
	Impurity D	: Not more than 0.2%	<0.01 %
	Impurity E	: Not more than 0.2%	<0.01 %
	Impurity F	: Not more than 0.2%	<0.01 %
	Impurity G	: Not more than 0.2%	<0.01 %
	Impurity H	: Not more than 0.2%	0.05 %
	Impurity I	: Not more than 0.2%	<0.01 %
	Impurity J	: Not more than 0.2%	0.05 %
	Impurity K	: Not more than 0.10%	0.02 %
	Unspecified impurities	: Not more than 0.10%	<0.01 %
	Sum of impurities other than A	: Not more than 0.5%	0.14 %
Residual solvents	Ethyl acetate	: Not more than 500 ppm	63 ppm
	Ethanol	: Not more than 3500 ppm	1252 ppm
	Chloroform	: Not more than 50 ppm	4 ppm

Complies Eur. Ph. 8.7th Edition

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