Lote: 0130917

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QUALITY CONTROL LABORATORY CERTIFICATE OF ANALYSIS	**RANITIDINE HYDROCHLORIDE (Form II)**

Batch No: 12001710145 **Manufacturing date:** 10 / 07 / 2017

Analysis number: 51947 **Retest date:** July - 2020

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	5.3
Loss on drying	Maximum 0.75%	0.12%
Sulfated ash	Maximum 0.1%	0.05%
Heavy metals	Maximum 20 ppm	Complies

Complies Eur. Ph. 9.2

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

DATE OF RELEASE: 01 / August / 2017 APPROVED

QC Manager
Anna Molina

QA Plant Responsible
Georgina Lidón

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Batch No: 12001710145 **Manufacturing date:** 10 / 07 / 2017

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TEST	REQUIREMENTS		RESULTS
Assay	98.5% to 101.5% (on dried substance)		100.2 %
Related substances (HPLC)	Impurity A	: Not more than 0.3%	0.07 %
	Impurity B	: Not more than 0.10%	<0.05 %
	Impurity C	: Not more than 0.10%	<0.05 %
	Impurity D	: Not more than 0.10%	<0.05 %
	Impurity E	: Not more than 0.10%	<0.05 %
	Impurity F	: Not more than 0.10%	<0.05 %
	Impurity G	: Not more than 0.10%	<0.05 %
	Impurity H	: Not more than 0.10%	<0.05 %
	Impurity I	: Not more than 0.10%	<0.05 %
	Impurity J	: Not more than 0.15%	<0.05 %
	Impurity K	: Not more than 0.10%	<0.05 %
	Unspecified impurities	: Not more than 0.10%	<0.05 %
	Total	: Not more than 0.5%	0.1 %
Residual solvents	Ethyl acetate	: Not more than 500 ppm	12 ppm
	Ethanol	: Not more than 3500 ppm	299 ppm
	Chloroform	: Not more than 50 ppm	1 ppm

Complies Eur. Ph. 9.2

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