Lote: 0J2.1217

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

Batch No:	12001710169	**Manufacturing date:**	22 / 09 / 2017
Analysis number:	52186	**Retest date:**	September - 2020

TEST	REQUIREMENTS		RESULTS
Appearance	White or pale yellow, crystalline powder, hygroscopic		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%		0.09 %
Sulfated ash	Maximum 0.1%		0.04 %
Heavy metals	Maximum 20 ppm		Complies
Assay	98.5% to 101.5% (on dried substance)		99.9 %
Related substances (HPLC)	Impurity A	: Not more than 0.3%	0.06 %
	Impurity J	: Not more than 0.15%	<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	10 ppm
	Ethanol	: Not more than 3500 ppm	216 ppm
	Chloroform	: Not more than 50 ppm	1 ppm

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)

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7).

DATE OF RELEASE: 06 / October / 2017

APPROVED

QC Manager
Anna Molina

QA Plant Responsible
Georgina Lidón