Lote: 080313

UNION QUIMICO FARMACEUTICA, S.A.

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

Batch No: 12001310019 **Manufacturing date:** 01 / 02 / 2013

Analysis number: 43746 **Retest date:** February - 2016

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 BY	Complies
pH (1% Water)	4.5 to 6.0	5.4
Loss on drying	Maximum 0.75%	0.27 %
Sulfated ash	Maximum 0.1%	0.06 %
Heavy metals	Maximum 20 ppm	Complies
Assay	98.5% to 101.5% (on dried substance)	100.1 %

Complies Eur. Ph. 7th Edition

MANUFACTURING FACILITY:
UNION QUIMICO FARMACEUTICA, S.A.
Polígon Industrial El Pla, Avda. Puigcerdà nº9, C-17, Km 17.4, 08185 LLIÇÀ DE VALL (Barcelona) Spain.

DATE OF RELEASE: 21 / February / 2013

APPROVED

p.o.

QUALITY CONTROL MANAGER
M.Borrás

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TEST	REQUIREMENTS		RESULTS
Related substances (HPLC)	Impurity A	: Not more than 0.5%	0.04 %
	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%	<0.01%
	Impurity I	: Not more than 0.2%	<0.01 %
	Impurity J	: Not more than 0.2%	0.02 %
	Impurity K	: Not more than 0.10%	<0.01 %
	Unspecified impurities	: Not more than 0.10%	0.01 %
	Sum of impurities other than A	: Not more than 0.5%	0.06 %
Residual solvents	Ethyl acetate	: Not more than 500 ppm	< 11 ppm
	Ethanol	: Not more than 3500 ppm	232 ppm
	Chloroform	: Not more than 50 ppm	< 1 ppm

Complies Eur. Ph. 7th Edition

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