

UNION QUIMICO FARMACEUTICA, S.A.

QUALITY CONTROL LABORATORY CERTIFICATE OF ANALYSIS	RANITIDINE HYDROCHLORIDE (Form II)
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Batch No:	12001418004	Manufacturing date:	14 / 01 / 2014
Analysis number:	45510	Retest date:	January - 2017

<u>TEST</u>	<u>REQUIREMENTS</u>	<u>RESULTS</u>
Appearance	White or pale yellow, crystalline powder	Complies
Identification A (IR)	Same bands as the reference standard	Positive
Identification B (CI)	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%	0.31 %
Sulfated ash	Maximum 0.1%	0.09 %
Heavy metals	Maximum 20 ppm	Complies
Assay	98.5% to 101.5% (on dried substance)	100.6 %

Complies Eur. Ph. 8th Edition

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

DATE OF RELEASE: 12 / February / 2014

APPROVED



QUALITY CONTROL MANAGER
 M. Borrás

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TEST	REQUIREMENTS	RESULTS
Related substances (HPLC)	Impurity A : Not more than 0.5%	0.11 %
	Impurity B : Not more than 0.2%	0.02 %
	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%	0.05 %
Residual solvents	Ethyl acetate : Not more than 500 ppm	<11 ppm
	Ethanol : Not more than 3500 ppm	234 ppm
	Chloroform : Not more than 50 ppm	2 ppm

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