

UNION QUIMICO FARMACEUTICA, S.A.

QUALITY CONTROL LABORATORY CERTIFICATE OF ANALYSIS	RANITIDINE HCl (Form II)
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Batch No: 12001210031

Manufacturing date: 12 / 03 / 2012

Analysis No: 42337

Retest date: March - 2015

TEST	REQUIREMENTS	RESULTS
Description	An white or pale yellow, crystalline powder.	Positive
Identification A (IR)	Same bands as the standard.	Complies
Identification B (Cl)	Qualitative test	Complies
Appearance of solution	Clear and nmt BY5	Complies
pH (1% H_2O)	4.5 - 6.0	5.2
Loss on drying	Not more than 0.75%	0.10%
Sulphated ash	Not more than 0.1%	0.05%
Heavy metals	Not more than 20 ppm	Complies
Related substances (HPLC)	Impurity A : nmt 0.5% Impurity B : nmt 0.2% Impurity C : nmt 0.2% Impurity D : nmt 0.2% Impurity E : nmt 0.2% Impurity F : nmt 0.2% Impurity G : nmt 0.2% Impurity H : nmt 0.2% Impurity I : nmt 0.2% Impurity J : nmt 0.2% Impurity K : nmt 0.1% Any other impurity : nmt 0.10% Sum of impurities other than A: nmt 0.5%	0.06% 0.01% 0.01% < 0.01% < 0.01% 0.01% < 0.01% < 0.01% < 0.01% 0.04% < 0.01% 0.01% 0.10%

Complies Eur. Ph. 7th. Edition

MANUFACTURING FACILITY:

UNION QUIMICO FARMACEUTICA, S.A.

Poligono Industrial El Pla, Av. Puigcerdà No. 9, C - 17, km 17.4, 08185 Lliçà de Vall (Barcelona) Spain

DATE OF RELEASE: 30 / March / 2012

APPROVED

[Signature]

QUALITY CONTROL MANAGER
M. Borrás

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Residual solvents	Ethyl acetate : nmt 500 ppm Ethanol : nmt 3500 ppm Chloroform : nmt 50 ppm	106 ppm 1618 ppm 5 ppm
Assay	98.5% - 101.5% on dried subst.	100.6%

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