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UNION QUIMICO FARMACEUTICA, S.A.

QUALITY CONTROL LABORATORY
CERTIFICATE OF ANALYSIS

COMPACTED
RANITIDINE HCl

Batch No: 12071310083 Manufacturing date: 21/05/2013
Certificate number: 40959 Retest date: May - 2016

TEST	REQUIREMENTS	RESULTS
Description	White or pale-yellow crystalline powder	Complies
Identification A (IR)	Passes test	Passes test
Identification B	Passes test	Passes test
Appearance of solution	Clear and not more coloured than BY5	Passes test
pH (1% in water)	4,5-6,0	5,2
Loss on drying	max. 0,75%	0,02%
Sulphated ash	max. 0.1%	0,06%
Heavy metals	max. 20ppm	Complies
Assay	98,5-101,5% on dried substance	100,1 %

RESIDUAL SOLVENTS:

Ethyl alcohol	max. 3500ppm	2899ppm
Ethyl acetate	max. 500ppm	169 ppm
Chloroform	max. 50ppm	4 ppm

There is no potential for other listed class 1 solvents to be present and that the material, if tested, will comply with the established standards.

Complies Eur. Ph. 7th Edition

MANUFACTURING SITE:

UNION QUIMICO FARMACEUTICA S.A.

Polig.Ind. Molí de les Planes, C/ Font de Bocs s/nº, 08470 - Sant Celoni (Barcelona) Spain

DATE OF RELEASE: 14/06/2013

APPROVED

M. Borrás

QUALITY CONTROL MANAGER
M. Borrás

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RESPONSIBLE CARE
El Compromiso de la Industria Química
con el Desarrollo Sostenible

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