

**QUALITY CONTROL LABORATORY**  
**CERTIFICATE OF ANALYSIS**

**RANITIDINE**  
**HYDROCHLORIDE (Form II)**

**Batch No:** 12001610121      **Manufacturing date:** 09 / 09 / 2016  
**Analysis number:** 50313      **Retest date:** September - 2019

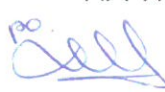
<u>TEST</u>	<u>REQUIREMENTS</u>	<u>RESULTS</u>
<b>Appearance</b>	White or pale yellow, crystalline powder	Complies
<b>Identification A (IR)</b>	Same bands as the reference standard	Positive
<b>Identification B (CI)</b>	Qualitative test	Positive
<b>Appearance of solution</b>	Clear and not more intensely coloured than BY5	Complies
<b>pH (1% Water)</b>	4.5 to 6.0	5.4
<b>Loss on drying</b>	Maximum 0.75%	0.30%
<b>Sulfated ash</b>	Maximum 0.1%	0.03%
<b>Heavy metals</b>	Maximum 20 ppm	Complies
<b>Assay</b>	98.5% to 101.5% (on dried substance)	100.1%

**Complies Eur. Ph. 8.7th Edition**

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) Spain.

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

DATE OF RELEASE: 26 / September / 2016      APPROVED

  
 QC Manager  
 Anna Molina

  
 QA Plant Responsible  
 Manuel Ron

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<u>TEST</u>	<u>REQUIREMENTS</u>	<u>RESULTS</u>
<b>Related substances (HPLC)</b>	Impurity A : Not more than 0.5%	0.09 %
	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%	0.04 %
	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%	0.07 %
<b>Residual solvents</b>	Ethyl acetate : Not more than 500 ppm	18 ppm
	Ethanol : Not more than 3500 ppm	403 ppm
	Chloroform : Not more than 50 ppm	1 ppm


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