

QUALITY CONTROL LABORATORY
CERTIFICATE OF ANALYSIS

RANITIDINE HYDROCHLORIDE
(Form II)

Batch No: 12002012004.01 Manufacturing date: 23 / 01 / 2020
Analysis number: 56527 Retest date: January - 2023

TEST	REQUIREMENTS	RESULTS
Appearance	White or pale yellow, crystalline powder, hygroscopic	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	5.5
Loss on drying	Maximum 0.75%	0.07 %
Sulfated ash	Maximum 0.1%	0.0 %
Assay	98.5% to 101.5% (on dried substance)	100.3 %
Related substances (HPLC)	Impurity A : Not more than 0.3%	<0.05 %
	Impurity J : Not more than 0.15%	<0.05 %
	Unspecified impurities : Not more than 0.10%	<0.05 %
	Total : Not more than 0.5%	0.1 %
Residual solvents	Ethyl acetate : Not more than 500 ppm	11 ppm
	Ethanol : Not more than 3500 ppm	282 ppm
	Chloroform : Not more than 50 ppm	0.5 ppm

Complies Eur. Ph. Current Edition

MANUFACTURING SITE:
UNION QUÍMICO FARMACÉUTICA, 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).

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APPROVED
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