lote 0417032D

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UQUIFA

QUALITY CONTROL LABORATORY CERTIFICATE OF ANALYSIS	RANITIDINE HYDROCHLORIDE (Form II)

Batch No:	12002012004.02	**Manufacturing date:**	27 / 01 / 2020
Analysis number:	56528	**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 (Cl)	Qualitative test		Positive
Appearance of solution	Clear and not more intensely coloured than BY5		Complies
pH (1% Water)	4.5 to 6.0		5.4
Loss on drying	Maximum 0.75%		0.08 %
Sulfated ash	Maximum 0.1%		<0.1 %
Assay	98.5% to 101.5% (on dried substance)		100.2 %
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	279 ppm
	Chloroform	: Not more than 50 ppm	0.5 ppm

Complies Eur. Ph. Current 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: 27 / February / 2020 APPROVED

p.o.
QC Manager
Miriam Vilas

p.a.
QA Specialist
Eduard Muntalt

Responsible Care