METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1522-TDS-ENG-2020

RANITIDINA HCL (PH.EUR)		
DESCRIPTION DCI: RANITIDINE HYDROCHLORIDE	DESCRIPTION DOE: RANITIDINA HIDROCLORURO	
CAS Nº: 66357-59-3	EC Nº: 266-333-0	AEMPS CODE: 2CH
MOL. WEIGHT: 350.87	MOL. FORMULA: C13H22N4O3S·HCl	ARTICLE CODE: 1522

ATTRIBUTES	SHOULD BE
Appearance	White or pale yellow, crystalline powder, hygroscopic
Solubility	Freely soluble in water, sparingly soluble or slightly soluble in anhydrous ethanol, very slightly soluble in methylene chloride
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY5
pH	4.5 - 6.0
Related substances	
Impurity A	=< 0.3 %
Impurity J	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total of impurities	=< 0.5 %
Loss on drying	=< 0.75 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.5 %
Residual solvents	
Ethanol	=< 3500 ppm
Ethyl acetate	=< 500 ppm
Chloroform	=< 50 ppm

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Keep tightly closed between 2 and 8 ºC.

REMARKS

Ranitidine HCl form II is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.

The above information does not exempt from the obligation to identify the product before use.