



## TECHNICAL DATA SHEET

0394-TDS-ENG-2024

CIMETIDINA (EUR. PH.)		
DESCRIPTION DCI: cimetidine		DESCRIPTION DOE: CIMETIDINA
CAS Nº: 51481-61-9	EC Nº: 257-252-2	AEMPS CODE: 598A
MOL. WEIGHT: 252,34	MOL. FORMULA: C10H16N6S	ARTICLE CODE: 0394

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Slightly soluble in water, soluble in ethanol (96 %), practically insoluble in methylene chloride. It dissolves in dilute mineral acids
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y5
Related substances	
Impurity B	=< 0.2 %
Impurity C	=< 0.2 %
Impurity D	=< 0.2 %
Impurity E	=< 0.2 %
Impurity F	=< 0.2 %
Impurity G	=< 0.2 %
Impurity H	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.0 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.2 %
Assay	98.5 - 101.5 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Store in a well-ventilated place. Keep container tightly closed.

### REMARKS

It shows polymorphism (5.9).

Cimetidine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

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.