

**CIMETIDINA (EUR. PH.)**

PRODUCT CODE: 0394	CAS Nº: 51481-61-9	ANALYSIS Nº: 296/23
MANUFACTURER BATCH: 10402000019101	CERTIFICATE ID: 40.409	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 24/10/2023	
METAPH BATCH: 0041223	RETEST DATE: 22/10/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y5	Complies
Related substances		
Impurity B	=< 0.2 %	< 0.05 %
Impurity C	=< 0.2 %	Not detected
Impurity D	=< 0.2 %	0.15 %
Impurity E	=< 0.2 %	< 0.05 %
Impurity F	=< 0.2 %	< 0.05 %
Impurity G	=< 0.2 %	< 0.05 %
Impurity H	=< 0.2 %	Not detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	0.15 %
Loss on drying	=< 0.5 %	0.08 %
Sulfated ash	=< 0.2 %	=< 0.2 %
Assay	98.5 - 101.5 %	100.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

It shows polymorphism (5.9).

All data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

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

Analysis date: 04/01/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000248
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