METAPHARMACEUTICAL IND SL
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CIMETIDINA (EUR. PH.)

PRODUCT CODE: 0394	CAS Nº: 51481-61-9	ANALYSIS Nº: 271/24	
MANUFACTURER BATCH:	10402000022701	CERTIFICATE ID:	43.960
SUPPLIER BATCH:	----	MANUFACTURING DATE:	19/09/2024
METAPH BATCH:	0251024	RETEST DATE:	18/09/2029

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 %	< 0.05 %
Impurity D	=< 0.2 %	< 0.05 %
Impurity E	=< 0.2 %	< 0.05 %
Impurity F	=< 0.2 %	< 0.05 %
Impurity G	=< 0.2 %	0.1 %
Impurity H	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	0.05 %
Total impurities	=< 1.0 %	0.1 %
Loss on drying	=< 0.5 %	< 0.01 % (*)
Sulfated ash	=< 0.2 %	0.04 % (*)
Assay	98.5 - 101.5 %	99.3 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

It shows polymorphism.

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

(*) Data controlled by Metapharmaceutical Industrial SL.

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: 07/11/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000248