



## TRIMETOPRIM (EUR. PH.)

PRODUCT CODE: 1847	CAS Nº: 738-70-5	ANALYSIS Nº: 069/24
MANUFACTURER BATCH: A-20112301026	CERTIFICATE ID: 41.513	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 14/01/2023	
METAPH BATCH: 0230324	RETEST DATE: 31/12/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white powder	White powder
Identification C	Complies	Complies
Appearance of solution	Not more intensely coloured than ref. sol. BY7	Complies
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.2 %	< 0.05 %
Impurity K	=< 5 ppm	< 5 ppm
Loss on drying	=< 1.0 %	0.03 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 101.0 %	100.2 %

### COMPLIES WITH

European Pharmacopoeia 11.3

### REMARKS

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

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

### STORAGE

Store in a cool place. Keep the container tightly closed in a dry and ventilated place.

Analysis date: 08/05/2024  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000302  
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