



TECHNICAL DATA SHEET

1847-TDS-ENG-2024

TRIMETOPRIM (EUR. PH.)		
DESCRIPTION DCI: trimethoprim		DESCRIPTION DOE: TRIMETOPRIMA
CAS Nº: 738-70-5	EC Nº: 212-006-2	AEMPS CODE: 90A
MOL. WEIGHT: 290,32	MOL. FORMULA: C ₁₄ H ₁₈ N ₄ O ₃	ARTICLE CODE: 1847

ATTRIBUTES	SHOULD BE
Appearance	White or yellowish-white powder
Solubility	Very slightly soluble in water, slightly soluble in ethanol (96 %), practically insoluble in heptane
Identification C	Complies
Appearance of solution	Not more intensely coloured than ref. sol. BY7
Related substances	
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.2 %
Impurity K	=< 5 ppm
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.3

STORAGE

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

REMARKS

Trimethoprim 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.