



TECHNICAL DATA SHEET

151373-TDS-ENG-2025

MUPIROCINA (EUR. PH.)		
DESCRIPTION DCI: mupirocin		DESCRIPTION DOE: MUPIROCINA
CAS Nº: 12650-69-0	EC Nº: 603-145-3	AEMPS CODE: 2317A
MOL. WEIGHT: 500,62	MOL. FORMULA: C ₂₆ H ₄₄ O ₉	ARTICLE CODE: 151373

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Slightly soluble in water, freely soluble in acetone, in anhydrous ethanol and in methylene chloride
Identification	Complies
pH	3.5 - 4.0
Specific optical rotation	-21 / -17
Related substances	
Impurity C	=< 4 %
Any other impurity	=< 1 %
Total impurities	=< 6 %
Water	=< 1.0 %
Assay	93.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store between 2 - 8 °C. Protected from light.

REMARKS

It shows polymorphism.

Mupirocin 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.