



MUPIROCINA (EUR. PH.)

PRODUCT CODE: 151373	CAS Nº: 12650-69-0	ANALYSIS Nº: 318/25
MANUFACTURER BATCH: MUP25-25	CERTIFICATE ID: 48.624	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/09/2025	
METAPH BATCH: 0101025	EXPIRY DATE: 30/08/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White white powder
Solubility	Slightly soluble in water, freely soluble in acetone, in anhydrous ethanol and in methylene chloride	Complies (*)
Identification	Complies	Complies
pH	3.5 - 4.0	3.7
Specific optical rotation	-21 / -17	-20
Related substances		
Impurity C	=< 4 %	1.1 %
Any other impurity	=< 1 %	< 1 % (#)
Total impurities	=< 6 %	3.6 %
Water	=< 1.0 %	0.3 %
Assay	93.0 - 102.0 %	98.2 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Impurities detailed underneath:

RT (2.05 min) = 0.15 %
RT (3.50 min) = 0.45 %
RT (5.05 min) = 0.77 %
RT (5.36 min) = 0.57 %
RT (18.18 min) = 0.19 %
RT (21.04 min) = 0.19 %

It shows polymorphism.

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

Mupirocin 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.

(*) Data adapted from the manufacturer's certificate of analysis.

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.

Analysis date: 15/10/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001128
BILLS BIOTECH PVT. LTD.
Plot No.-P/01, Biotech Park Phase-1, GIDC,
Manjusr Industrial Estate
Village-Manjusr,



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STORAGE

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

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