

MITOMICINA (EUR. PH.)

PRODUCT CODE: 151374	CAS Nº: 50-07-7	ANALYSIS Nº: 270/24
MANUFACTURER BATCH: 1127011N240301	CERTIFICATE ID: 43.958	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 31/03/2024	
METAPH BATCH: 0241024	EXPIRY DATE: 30/03/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Blue-violet crystals or crystalline powder	Blue-violet crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
pH	5.5 - 7.5	5.7
Related substances		
Impurity A	=< 0.5 %	< 0.05 %
Impurity B	=< 0.5 %	Not Detected
Impurity C	=< 0.5 %	Not Detected
Impurity D	=< 0.5 %	Not Detected
Any other impurity	=< 0.5 %	0.07 %
Total impurities	=< 2.0 %	0.07 %
Water	=< 2.5 %	0.4 %
Bacterial endotoxines	< 10 IU/mg	< 0.5 IU/mg (*)
Assay	97.0 - 102.0 %	100.9 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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

(*) 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.

STORAGE

Keep container tightly closed. Keep container in a cool, well-ventilated area. Sensitive to light.

Analysis date: 02/12/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001479
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