



## TECHNICAL DATA SHEET

151374-TDS-ENG-2024

MITOMICINA (EUR. PH.)		
DESCRIPTION DCI: mitomycin		DESCRIPTION DOE: MITOMICINA
CAS N°: 50-07-7	EC N°: 200-008-6	AEMPS CODE: 431A
MOL. WEIGHT: 334,33	MOL. FORMULA: C <sub>15</sub> H <sub>18</sub> N <sub>4</sub> O <sub>5</sub>	ARTICLE CODE: 151374

ATTRIBUTES	SHOULD BE
Appearance	Blue-violet crystals or crystalline powder
Solubility	Slightly soluble in water, freely soluble in dimethylacetamide, sparingly soluble in methanol, slightly soluble in acetone
Identification A	Complies
Identification B	Complies
pH	5.5 - 7.5
Related substances	
Impurity A	=< 0.5 %
Impurity B	=< 0.5 %
Impurity C	=< 0.5 %
Impurity D	=< 0.5 %
Any other impurity	=< 0.5 %
Total impurities	=< 2.0 %
Water	=< 2.5 %
Bacterial endotoxines	< 10 IU/mg
Assay	97.0 - 102.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

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

### REMARKS

Mitomycin 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.