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Mitomycin for Injection

DEFINITION

Mitomycin for Injection contains NLT 90.0% and NMT 120.0% of the labeled amount of mitomycin ($C_{15}H_{18}N_4O_5$).

IDENTIFICATION

• **A.** The retention time of the major peak from the *Sample solution* corresponds to that from the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Dissolve 1.54 g of ammonium acetate in 250 mL of methanol. Add 5.0 mL of 0.83 N acetic acid and water to make 1000 mL.

System suitability solution: 0.5 mg/mL of USP Mitomycin RS and 7.5 mg/mL of 3-ethoxy-4-hydroxy benzaldehyde in *N,N*-dimethylacetamide

Standard solution: 0.5 mg/mL of USP Mitomycin RS in *N,N*-dimethylacetamide

Sample solution: Add an accurately measured volume of *N,N*-dimethylacetamide to 1 container of Mitomycin for Injection to obtain a solution that is nominally 0.5 mg/mL of mitomycin.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 365 nm

Column: 3.9-mm × 30-cm; 10-µm packing L11

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for mitomycin and 3-ethoxy-4-hydroxybenzaldehyde are 1.0 and 1.4, respectively.]

Suitability requirements

Resolution: NLT 1.8 between mitomycin and 3-ethoxy-4-hydroxybenzaldehyde, *System suitability solution*

Tailing factor: NMT 1.3, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mitomycin ($C_{15}H_{18}N_4O_5$) in the container of Mitomycin for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times F \times 100$$

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of USP Mitomycin RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of mitomycin in the *Sample solution* (mg/mL)

P = potency of mitomycin in USP Mitomycin RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: Constitute as directed in the labeling.

Acceptance criteria: 6.0–8.0 where it contains mannitol, and 5.5–8.5 where it contains hydroxypropyl betadex

• **Water Determination,** *Method Ia* **⟨921⟩**

Sample solution: Prepare as directed for a hygroscopic specimen, using the pooled contents of five containers.

Acceptance criteria: NMT 5.0%

• **Bacterial Endotoxins Test ⟨85⟩:** Contains NMT 10.0 USP Endotoxin Units/mg of mitomycin

• **Sterility Tests ⟨71⟩:** Meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined, Membrane Filtration*

• **Constituted Solution:** At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

• **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*, protected from light. Store at 25°, excursions permitted between 15° and 30°.

• **USP Reference Standards ⟨11⟩**

USP Mitomycin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MITOMYCIN FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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