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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    | <a href="#">Documentary Standards Support</a>                               | SM12020 Small Molecules 1 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | SM12020 Small Molecules 1 |

**Chromatographic Database Information:** [Chromatographic Database](#)

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