

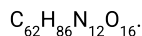
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## Dactinomycin for Injection

### DEFINITION

Dactinomycin for Injection is a sterile mixture of Dactinomycin and Mannitol. It contains NLT 90.0% and NMT 120.0% of the labeled amount of



[CAUTION—Great care should be taken to prevent inhaling particles of Dactinomycin and exposing the skin to it.]

### IDENTIFICATION

#### • A. PROCEDURE

**Standard solution:** 25 µg/mL of [USP Dactinomycin RS](#) in methanol

**Sample solution:** 25 µg/mL of dactinomycin in methanol

**Acceptance criteria:** The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as the *Standard solution*, concomitantly measured.

**Ratio:**  $A_{240}/A_{445}$  1.30–1.50

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

### ASSAY

#### • PROCEDURE

[NOTE—Use freshly prepared *Standard solution* and *Sample solution*, protected from light.]

**Mobile phase:** Acetonitrile and water (3:2)

**Standard solution:** 250 µg/mL of [USP Dactinomycin RS](#) in *Mobile phase*

**Sample solution:** 250 µg/mL of dactinomycin from Dactinomycin for Injection diluted with *Mobile phase*. Filter, if necessary, to obtain a clear solution. [NOTE—Prepare the solution by adding a suitable aliquot of *Mobile phase* to one container of Dactinomycin for Injection.]

#### Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 3.9-mm × 30-cm; packing L1

**Flow rate:** 2.5 mL/min

**Injection size:** 10 µL

#### System suitability

**Sample:** *Standard solution*

[NOTE—The retention time for dactinomycin is 6 min.]

#### Suitability requirements

**Column efficiency:** NLT 1200 theoretical plates

**Tailing factor:** NMT 2

**Relative standard deviation:** NMT 3.0%

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of  $\text{C}_{62}\text{H}_{86}\text{N}_{12}\text{O}_{16}$  in the portion of Dactinomycin for Injection taken:

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

$r_U$  = peak response from the *Sample solution*

$r_S$  = peak response from the *Standard solution*

$C_S$  = concentration of [USP Dactinomycin RS](#) in the *Standard solution* (µg/mL)

$C_U$  = nominal concentration of dactinomycin in the *Sample solution* (µg/mL)

**Acceptance criteria:** 90.0%–120.0%

#### SPECIFIC TESTS

- **pH (791):** 5.5–7.5, in the solution constituted as directed in the labeling
- **LOSS ON DRYING (731):** Dry a portion in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h: it loses NMT 4.0% of its weight.
- **OTHER REQUIREMENTS:** It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).
- **BACTERIAL ENDOTOXINS TEST (85):** NMT 100.0 USP Endotoxin Units/mg of dactinomycin.
- **STERILITY TESTS (71):** Meets the requirements when tested as directed for *Test for Sterility of the Product to be Examined, Membrane Filtration*, each container being constituted aseptically by injecting Sterile Water for Injection through the stopper, and the entire contents of all the containers being collected aseptically with the aid of 200 mL of *Fluid A* before filtering.
- **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](#) and for [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#).

#### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging, Packaging for constitution](#); protect from light.
- **LABELING:** Label it to include the statement “Protect from light.”
- **USP REFERENCE STANDARDS (11):**  
[USP Dactinomycin RS](#)

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DACTINOMYCIN FOR INJECTION	<a href="#">Documentary Standards Support</a>	SM12020 Small Molecules 1

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

#### Most Recently Appeared In:

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