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Dactinomycin

Change to read:

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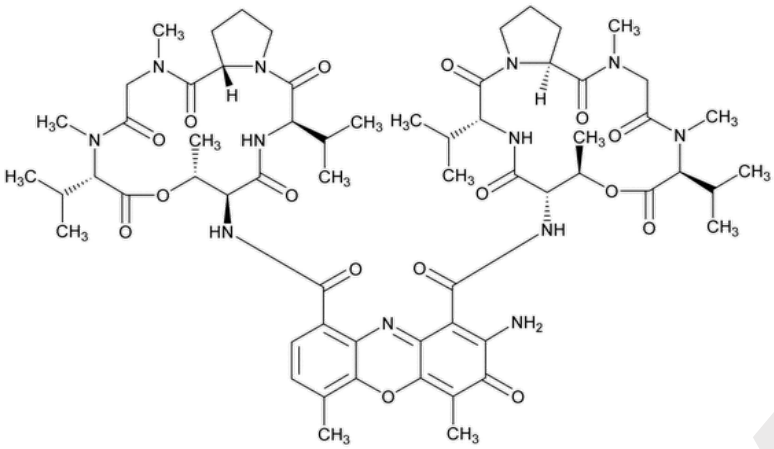

▲ (ERR 1-Jul-2021)

$C_{62}H_{86}N_{12}O_{16}$ 1255.42

Actinomycin D CAS RN®: 50-76-0; UNII: 1CC1JFE158.

DEFINITION

Dactinomycin contains NLT 950 µg/mg and NMT 1030 µg/mg of dactinomycin ($C_{62}H_{86}N_{12}O_{16}$), calculated on the dried basis.

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

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U

Standard solution: 25 µg/mL of dactinomycin from USP Dactinomycin RS in methanol

Sample solution: 25 µg/mL in methanol

Analytical wavelengths: 240 and 445 nm

Acceptance criteria

Absorptivity: The absorptivity, calculated on the dried basis, of the *Sample solution* at 445 nm is NLT 95.0% and NMT 103.0% that of the *Standard solution*.

Ratio: A_{240}/A_{445}, 1.30–1.50, *Sample solution*

• **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**

Mobile phase: Acetonitrile, 0.04 M sodium acetate, and 0.07 M acetic acid (46:25:25). Pass through a filter of 1-µm or finer pore size. The acetonitrile concentration may be varied to provide appropriate chromatographic system performance and a suitable elution time.

Standard solution: 1.2 mg/mL of USP Dactinomycin RS in *Mobile phase*. Use a freshly prepared solution, and protect it from light.

Sample solution: 1.2 mg/mL of Dactinomycin in *Mobile phase*. Use a freshly prepared solution, and protect it from light.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for dactinomycin is about 25 min.]

Suitability requirements

Relative standard deviation: NMT 1.0%, dactinomycin (3 replicate injections)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the potency, in µg/mg, of dactinomyin ($C_{62}H_{86}N_{12}O_{16}$) in the Dactinomycin taken:

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

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* (mg/mL)

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

P = potency of dactinomycin in USP Dactinomycin RS (mg/mg)

F = conversion factor, 1000 µg/mg

Acceptance criteria: 950–1030 µg/mg on the dried basis

SPECIFIC TESTS

- **OPTICAL ROTATION,** *Specific Rotation* ⟨781S⟩

  Sample solution: 1 mg/mL in methanol

  Acceptance criteria: −293° to −329° (*t* = 20°)
- **CRYSTALLINITY** ⟨695⟩**:** Meets the requirements
- **LOSS ON DRYING** ⟨731⟩

  Analysis: Dry under vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h.

  Acceptance criteria: NMT 5.0%
- **BACTERIAL ENDOTOXINS TEST** ⟨85⟩**:** It contains NMT 100 USP Endotoxin Units/mg.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light and excessive heat.
- **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	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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