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Minocycline for Injection

DEFINITION

Minocycline for Injection is sterile, freeze-dried Minocycline Hydrochloride suitable for parenteral use. It contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of minocycline ($C_{23}H_{27}N_3O_7$).

IDENTIFICATION

• **A.** 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: Dimethylformamide, tetrahydrofuran, 0.2 M ammonium oxalate, and 0.01 M edetate disodium (120:80:600:180). Adjust with ammonium hydroxide to a pH of 7.2.

System suitability solution: Dissolve 10 mg of USP Minocycline Hydrochloride RS in 20 mL of 0.2 M ammonium oxalate. Heat on a water bath at 60° for 3 h, allow to cool, and dilute with water to 25.0 mL.

Standard solution: 0.5 mg/mL of minocycline from USP Minocycline Hydrochloride RS in water. Use this solution within 3 h.

Sample solution 1 (where it is represented as being in a single-dose container)**:** Nominally 0.5 mg/mL of minocycline, prepared as follows. Constitute Minocycline for Injection in a volume of water, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a hypodermic needle and syringe, and dilute with water.

Sample solution 2 (where the label states the quantity of minocycline in a given volume of constituted solution)**:** Nominally 0.5 mg/mL of minocycline, prepared as follows. Constitute Minocycline for Injection in a volume of water, corresponding to the volume of solvent specified in the labeling. Dilute a portion of constituted solution with water.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

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

[Note—The relative retention times for epiminocycline and minocycline are 0.7 and 1.0, respectively.]

Suitability requirements

Capacity factor: 5.0–11.5, *Standard solution*

Resolution: NLT 4.6 between epiminocycline and minocycline, *System suitability solution*

Tailing factor: 0.9–2.0 for minocycline, *Standard solution*

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

Analysis

Samples: *Standard solution*, and *Sample solution 1* or *Sample solution 2*

Calculate the percentage of the labeled amount of minocycline ($C_{23}H_{27}N_3O_7$) in the container, or in the portion of constituted solution taken:

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

r_U = peak response from *Sample solution 1* or *Sample solution 2*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of *Sample solution 1* or *Sample solution 2* (mg/mL)

P = potency of minocycline in USP Minocycline Hydrochloride 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

IMPURITIES

• **Limit of Epiminocycline**

Mobile phase, System suitability solution, Standard solution, Sample solution 1 or **Sample solution 2, Chromatographic system,** and **System suitability:** Proceed as directed in the *Assay*.

[Note—The relative retention times for epiminocycline and minocycline are 0.7 and 1.0, respectively.]

Analysis: Calculate the percentage of epiminocycline in the portion of Minocycline for Injection taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area of epiminocycline from *Sample solution 1* or *Sample solution 2*

r_T = total area of all the peaks from *Sample solution 1* or *Sample solution 2*

Acceptance criteria: NMT 6.0%

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: Nominally 10 mg/mL of minocycline

Acceptance criteria: 2.0–3.5

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

Test preparation: Prepare as directed for a hygroscopic specimen.

Acceptance criteria: NMT 3.0%

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 1.25 USP Endotoxin Units/mg of minocycline.

• **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:** It meets the requirements 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*, protected from light.

• **USP Reference Standards ⟨11⟩**

USP Minocycline Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
MINOCYCLINE 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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