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Dexmedetomidine Injection

DEFINITION

Dexmedetomidine Injection is a sterile solution containing Dexmedetomidine Hydrochloride and sodium chloride, suitable for dilution prior to intravenous administration. It contains NLT 90.0% and NMT 110.0% of the labeled amount of dexmedetomidine free base ($C_{13}H_{16}N_2$). [NOTE—This monograph is not applicable to veterinary articles described under 21 CFR 522.558.]

IDENTIFICATION

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

• **B.** The UV absorption spectrum of the major peak of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **PROCEDURE**

Buffer: Dissolve 2.4 g of disodium hydrogen phosphate heptahydrate and 0.14 g of monobasic sodium phosphate in 1 L of water. Adjust with 0.1 N phosphoric acid or 0.1 N sodium hydroxide to a pH of 7.8, if needed.

Mobile phase: Methanol and *Buffer* (600:400)

Diluent: 0.9% sodium chloride in water

Standard solution: 4.8 µg/mL of USP Dexmedetomidine Hydrochloride RS in water

Sample solution: Nominally equivalent to 4 µg/mL of dexmedetomidine in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm. For *Identification B*, use UV diode array, 200–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 50 µL

Run time: NLT 1.8 times the retention time of dexmedetomidine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dexmedetomidine ($C_{13}H_{16}N_2$) as free base in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of dexmedetomidine free base, 200.28

M_{r2} = molecular weight of dexmedetomidine hydrochloride, 236.74

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

Buffer and **Mobile phase:** Proceed as directed in the *Assay*.

Butylparaben stock solution: 0.25 mg/mL of butylparaben prepared as follows. To a suitable amount of butylparaben in a suitable volumetric flask, add methanol, 5% of total volume, and dilute with water to volume.

Butylparaben solution: 0.0025 mg/mL of butylparaben in water from *Butylparaben stock solution*

System suitability solution: Equivalent to 0.18 µg/mL of dexmedetomidine free base from USP Dexmedetomidine Hydrochloride RS and 0.25 µg/mL of butylparaben from *Butylparaben solution* in water

Standard solution: Equivalent to 0.2 µg/mL of dexmedetomidine free base from USP Dexmedetomidine Hydrochloride RS in water

Sensitivity solution: Equivalent to 0.04 µg/mL of dexmedetomidine free base from USP Dexmedetomidine Hydrochloride RS in water from the *Standard solution*

Sample solution: Use the neat Injection as is.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 25 µL

Run time: NLT 3 times the retention time of dexmedetomidine

System suitability

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

Suitability requirements

Resolution: NLT 4.0 between butylparaben and dexmedetomidine, *System suitability solution*

Relative standard deviation: NMT 10.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of dexmedetomidine from the *Standard solution*

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

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

M_{r1} = molecular weight of dexmedetomidine free base, 200.28

M_{r2} = molecular weight of dexmedetomidine hydrochloride, 236.74

Acceptance criteria: Disregard peaks below 0.02%.

Any individual impurity: NMT 0.5%

Total impurities: NMT 0.7%

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 2.5 USP Endotoxin Units/µg of dexmedetomidine free base

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

• **pH ⟨791⟩:** 4.5–7.0

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

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose, clear, glass vials. Store at controlled room temperature.

• **Labeling:** Label it to indicate that it is to be diluted with 0.9% Sodium Chloride Injection USP for intravenous use.

• **USP Reference Standards ⟨11⟩**

USP Dexmedetomidine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
DEXMEDETOMIDINE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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