

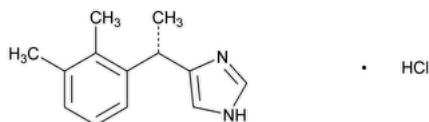
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Change to read:

Dexmedetomidine Hydrochloride

▲



▲ (ERR 1-Mar-2019)

$C_{13}H_{16}N_2 \cdot HCl$ 236.74

1*H*-Imidazole, 4-[1-(2,3-dimethylphenyl)ethyl]-, monohydrochloride, (S)-;

4-[(S)-α,2,3-Trimethylbenzyl]imidazole monohydrochloride CAS RN[®]: 145108-58-3; UNII: 1018WH7F9I.

DEFINITION

Dexmedetomidine Hydrochloride contains NLT 98.0% and NMT 102.0% of dexmedetomidine hydrochloride ($C_{13}H_{16}N_2 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *System suitability solution*, as obtained in the test for *Enantiomeric Purity*.
- **C.** [IDENTIFICATION TESTS—GENERAL, Chloride \(191\)](#): Meets the requirements

ASSAY

• PROCEDURE

Buffer: 0.89 g/L dibasic sodium phosphate dihydrate solution prepared as follows. Dissolve a suitable amount of dibasic sodium phosphate dihydrate with 90% of total volume of water, adjust with 16 g/L of monobasic sodium phosphate dihydrate solution in water to a pH of 7.0, and dilute with water to volume.

Mobile phase: Methanol and *Buffer* (60:40)

Standard solution: 0.2 mg/mL of [USP Dexmedetomidine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.2 mg/mL of Dexmedetomidine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4-mm × 12.5-cm; 5-μm packing L1

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dexmedetomidine hydrochloride ($C_{13}H_{16}N_2 \cdot HCl$) in the portion of the sample taken:

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

r_U = peak response of dexmedetomidine 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* (mg/mL)

C_u = concentration of Dexmedetomidine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

• ORGANIC IMPURITIES

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

Standard solution: 2 µg/mL of [USP Dexmedetomidine Hydrochloride RS](#) in *Mobile phase*

Sensitivity solution: 0.8 µg/mL of [USP Dexmedetomidine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 2 mg/mL of sample in *Mobile phase*

Chromatographic system: Proceed as directed in the Assay except for the following.

Run time: NLT 9 times the retention time of the dexmedetomidine peak

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

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

Relative standard deviation: NMT 5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—The relative retention times of known impurities are given in [Table 1](#).]

Table 1

Name	Relative Retention Time
Hydroxymedetomidine ^a	0.36
Dexmedetomidine	1.00
<i>N</i> -Benzyl hydroxymedetomidine ^b	2.22
Ethylmedetomidine ^c	2.47
<i>N</i> -Benzyl medetomidine ^d	6.25
<i>N</i> -Benzyl vinyl analog ^e	6.31

^a 1-(2,3-Dimethylphenyl)-1-(1*H*-imidazol-5-yl)ethanol.

^b 1-(1-Benzyl-1*H*-imidazol-5-yl)-1-(2,3-dimethylphenyl)ethanol.

^c 5-[1-(2,3-Dimethylphenyl)ethyl]-1-ethyl-1*H*-imidazole.

^d 1-Benzyl-5-[1-(2,3-dimethylphenyl)ethyl]-1*H*-imidazole.

^e 1-Benzyl-5-[1-(2,3-dimethylphenyl)vinyl]-1*H*-imidazole.

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

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

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

r_s = peak response of dexmedetomidine in the *Standard solution*

C_s = concentration of [USP Dexmedetomidine Hydrochloride RS](#) in the *Standard solution* (µg/mL)

C_u = concentration of Dexmedetomidine Hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: Disregard peaks below 0.04%.

Individual impurities: NMT 0.10%

Total impurities: NMT 0.3%

• ENANTIOMERIC PURITY