

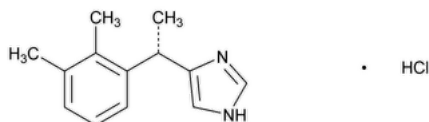
Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-543DD66B-772C-4A28-A96B-6C6EF6FE68BB_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M6080_05_01
 DOI Ref: pj6s3

© 2025 USPC
 Do not distribute

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
N-Benzyl hydroxymedetomidine ^b	2.22
Ethylmedetomidine ^c	2.47
N-Benzyl medetomidine ^d	6.25
N-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**

Buffer: To 1 L of 5.34 g/L dibasic sodium phosphate dihydrate solution, adjust with a suitable amount (about 700–800 mL) of 4.08 g/L monobasic potassium phosphate solution to a pH of 7.0.

Mobile phase: Acetonitrile and Buffer (35:165)

System suitability solution: 1 µg/mL of [USP Levomedetomidine RS](#) and 50 µg/mL of [USP Dexmedetomidine Hydrochloride RS](#) in Mobile phase

Standard solution: 0.5 µg/mL of [USP Levomedetomidine RS](#) in Mobile phase

Sensitivity solution: 0.05 µg/mL of [USP Levomedetomidine RS](#) in Mobile phase

Sample solution: 50 µg/mL of sample in Mobile phase

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4-mm × 10-cm; 5-µm packing L41

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between levomedetomidine and dexmedetomidine, System suitability solution

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

Relative standard deviation: NMT 3.0%, Standard solution

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of levomedetomidine hydrochloride in the portion of sample taken:

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

r_U = peak height of levomedetomidine in the Sample solution

r_S = peak height of levomedetomidine in the Standard solution

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

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

Acceptance criteria: See [Table 2](#).

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Levomedetomidine ^a	0.69	1.0
Dexmedetomidine	1.00	—

^a (R)-4-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole hydrochloride.

SPECIFIC TESTS

- [Loss on Drying \(731\)](#).

Sample: 1.0 g

Analysis: Dry the Sample at 105° for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Store at controlled room temperature in tight containers in a dry place.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Dexmedetomidine Hydrochloride RS](#)

[USP Levomedetomidine RS](#)

(R)-4-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole hydrochloride.

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

Topic/Question	Contact	Expert Committee
DEXMEDETOMIDINE HYDROCHLORIDE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 49(3)

Current DocID: GUID-543DD66B-772C-4A28-A96B-6C6EF6FE68BB_5_en-US

DOI: https://doi.org/10.31003/USPNF_M6080_05_01

DOI ref: [pj6s3](#)

OFFICIAL