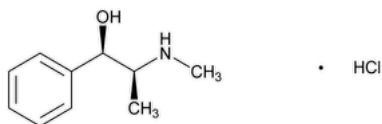


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Ephedrine Hydrochloride



$C_{10}H_{15}NO \cdot HCl$ 201.69

Benzenemethanol, α -[1-(methylamino)ethyl]-, hydrochloride, [*R*-(*R**,*S**)]-;

(-)-Ephedrine hydrochloride;

(1*R*,2*S*)-2-(Methylamino)-1-phenylpropan-1-ol hydrochloride; CAS RN®: 50-98-6; UNII: NLJ6390P1Z.

DEFINITION

Ephedrine Hydrochloride contains NLT 98.0% and NMT 102.0% of ephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197K▲ (CN 1-May-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Chloride](#): Meets the requirements
- **C.** The retention time of the ephedrine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 11.6 g/L of [ammonium acetate](#). Adjust with [glacial acetic acid](#) to a pH of 4.0.

Mobile phase: [Methanol](#) and *Buffer* (6:94)

Diluent: [Methanol](#) and [water](#) (6:94)

System suitability solution: 0.1 mg/mL each of [USP Ephedrine Hydrochloride RS](#) and [USP Pseudoephedrine Hydrochloride RS](#) in *Diluent*

Standard solution: 0.2 mg/mL of [USP Ephedrine Hydrochloride RS](#) in *Diluent*

Sample solution: 0.2 mg/mL of Ephedrine Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 257 nm

Column: 4.6-mm × 15-cm; 3-μm packing L11

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 2 times the retention time of ephedrine

System suitability

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

[NOTE—The relative retention times for ephedrine and pseudoephedrine are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 2.0 between ephedrine and pseudoephedrine, *System suitability solution*

Tailing factor: NMT 2.0 for ephedrine, *Standard solution*

Relative standard deviation: NMT 0.73% for ephedrine, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Ephedrine Hydrochloride taken:

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

r_U = peak response of ephedrine from the *Sample solution*

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

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

C_u = concentration of Ephedrine 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%

• [CHLORIDE AND SULFATE \(221\)](#), *Sulfate*

Sample solution: 1.25 mg/mL of Ephedrine Hydrochloride in water

Analysis: Add 1 mL of 3 N hydrochloric acid and 1 mL of barium chloride TS to 40 mL of the *Sample solution*.

Acceptance criteria: No turbidity develops within 10 min.

• **ORGANIC IMPURITIES**

Buffer, Mobile phase, and Chromatographic system: Proceed as directed in the Assay, except for the *Run time*.

Run time: NLT 2.5 times the retention time of ephedrine

System suitability solution: 0.1 mg/mL each of [USP Ephedrine Hydrochloride RS](#) and [USP Pseudoephedrine Hydrochloride RS](#) in *Mobile phase*

Sensitivity solution: 3.8 µg/mL of [USP Ephedrine Hydrochloride RS](#) in *Mobile phase*

Standard solution: 30 µg/mL of [USP Ephedrine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 7.5 mg/mL of Ephedrine Hydrochloride in *Mobile phase*

System suitability

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

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between ephedrine and pseudoephedrine, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of α -acetylbenzyl alcohol or any unspecified impurity in the portion of Ephedrine Hydrochloride taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (1/F) \times 100$$

r_u = peak response of α -acetylbenzyl alcohol or any unspecified impurity from the *Sample solution*

r_s = peak response of ephedrine from the *Standard solution*

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

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

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Ephedrine	1.0	—	—
Pseudoephedrine ^a	1.1	—	—
α -Acetylbenzyl alcohol ^b	1.4	2.5	0.2
Any unspecified impurity	—	1.0	0.1
Total impurities ^c	—	—	0.5

^a Included for identification only. It is not to be reported and not to be included in the total impurities.

^b (-)-(1R)-1-Hydroxy-1-phenylpropan-2-one.