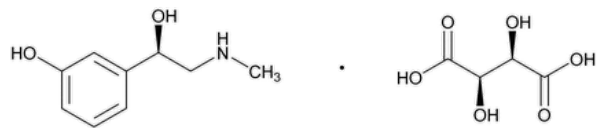


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Phenylephrine Bitartrate



$C_9H_{13}NO_2 \cdot C_4H_6O_6$ 317.29
Benzenemethanol, 3-hydroxy- α -[(methylamino)methyl]-, (2*R*,3*R*)-2,3-dihydroxybutanedioate (1:1) (salt);
(*R*)-(-)-*m*-Hydroxy- α -[(methylamino)methyl]benzyl alcohol hydrogen tartrate CAS RN[®]: 17162-39-9; UNII: 2703Q5ML57.

DEFINITION
Phenylephrine Bitartrate contains NLT 98.0% and NMT 102.0% of phenylephrine bitartrate ($C_9H_{13}NO_2 \cdot C_4H_6O_6$), 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, Tartrate \(191\)](#)
Sample: The alkaline filtrate from the test for [Optical Rotation \(781S\)](#), [Specific Rotation](#)
Acceptance criteria: The *Sample* responds positively to the test for *Tartrate* in [Identification Tests—General \(191\)](#).
- C.** 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**
Buffer: Dissolve 3.25 g of 1-octanesulfonic acid sodium salt monohydrate in 1 L of water, and adjust with 3 M phosphoric acid to a pH of 2.8.
Solution A: Acetonitrile and *Buffer* (10:90)
Solution B: Acetonitrile and *Buffer* (90:10)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	93	7
10	70	30
10.1	93	7
18	93	7

Diluent: *Solution A* and *Solution B* (80:20)
Standard solution: 0.6 mg/mL of [USP Phenylephrine Hydrochloride RS](#) in *Diluent*
Sample solution: 0.9 mg/mL of Phenylephrine Bitartrate in *Diluent*
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: LC
Detector: UV 215 nm

Column: 4.0-mm × 5.5-cm; 3-μm packing L1

Column temperature: 45°

Flow rate: 1.5 mL/min

Injection volume: 4 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.9

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of phenylephrine bitartrate ($C_9H_{13}NO_2 \cdot C_4H_6O_6$) in the portion of Phenylephrine Bitartrate taken:

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

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

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

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

C_U = concentration of Phenylephrine Bitartrate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of phenylephrine bitartrate, 317.29

M_{r2} = molecular weight of phenylephrine hydrochloride, 203.67

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

Buffer, Solution A, Solution B, Mobile phase, and Diluent: Proceed as directed in the Assay.

System suitability solution: 1.0 mg/mL of [USP Phenylephrine Hydrochloride RS](#) and 0.9 μg/mL each of [USP Norphenylephrine Hydrochloride RS](#) and [USP Phenylephrine Related Compound C RS](#) in *Diluent*

Standard solution: 0.001 mg/mL each of [USP Phenylephrine Hydrochloride RS](#), [USP Norphenylephrine Hydrochloride RS](#), [USP Phenylephrine Related Compound C RS](#), [USP Phenylephrine Related Compound D RS](#), and [USP Phenylephrine Related Compound E RS](#) in *Diluent*

Blank: 0.8 mg/mL of L(+)-tartaric acid in *Diluent*

Sample solution: 1.56 mg/mL of Phenylephrine Bitartrate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4-mm × 5.5-cm; 3-μm packing L1

Column temperature: 45°

Flow rate: 1.5 mL/min

Injection volume: 4 μL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between norphenylephrine and phenylephrine and NLT 1.5 between phenylephrine and phenylephrine related compound C, *System suitability solution*

Relative standard deviation: NMT 5% for norphenylephrine, phenylephrine, phenylephrine related compound C, phenylephrine related compound D, and phenylephrine related compound E, *Standard solution*

Analysis

Samples: *Standard solution*, *Blank*, and *Sample solution*

Examine the chromatogram of the *Blank* for the peaks, and disregard any corresponding peaks observed in the chromatogram of the *Sample solution*.