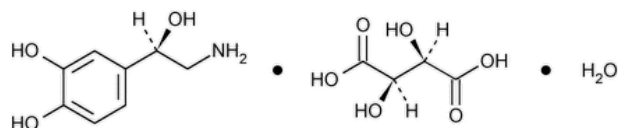


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Norepinephrine Bitartrate



$C_8H_{11}NO_3 \cdot C_4H_6O_6 \cdot H_2O$ 337.28

$C_8H_{11}NO_3 \cdot C_4H_6O_6$ 319.27

1,2-Benzenediol, 4-(2-amino-1-hydroxyethyl)-, (R)-, [R-(R*,R*)]-2,3-dihydroxybutanedioate (1:1) (salt), monohydrate;

(-)- α -(Aminomethyl)-3,4-dihydroxybenzyl alcohol tartrate (1:1) (salt), monohydrate CAS RN®: 108341-18-0; UNII: IFY5PE3ZRW.

Anhydrous CAS RN®: 51-40-1; UNII: ZW81GF408B.

DEFINITION

Norepinephrine Bitartrate contains NLT 97.0% and NMT 102.0% of $C_8H_{11}NO_3 \cdot C_4H_6O_6$, calculated on the anhydrous basis.

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K**

• **B. PROCEDURE**

Sample solution: 5 mg/mL in water

Analysis: Add 1 drop of ferric chloride TS to 2 mL of *Sample solution*.

Acceptance criteria: An intensely green color develops.

Change to read:

• **C. PROCEDURE**

Sample solution: $\blacktriangle$ 0.1 mg $\blacktriangle$ (ERR 1-Jan-2021) /mL

Analysis: Add 1.0 mL of 0.10 N iodine to 10 mL of the *Sample solution*. Allow to stand for 5 min, and add 2.0 mL of 0.10 N sodium thiosulfate.

Acceptance criteria: The solution is colorless, or has at most a slight pink or slight violet color (epinephrine and isoproterenol at the same pH, about 3.5, give a strong red-brown or violet color).

ASSAY

• **PROCEDURE**

Sample solution: Dissolve 500 mg of Norepinephrine Bitartrate in 20 mL of glacial acetic acid, warming slightly if necessary to effect solution.

Analysis: Add 2 drops of crystal violet TS to the *Sample solution*, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction (see [Titrimetry \(541\)](#)). Each mL of 0.1 N perchloric acid is equivalent to 31.93 mg of $C_8H_{11}NO_3 \cdot C_4H_6O_6$.

Acceptance criteria: 97.0%–102.0% on the anhydrous basis

IMPURITIES

INORGANIC IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%, from 200 mg

ORGANIC IMPURITIES

• **PROCEDURE: LIMIT OF ARTERENONE**

Sample solution: 2 mg/mL in water

Analysis: Determine the absorptivity of the *Sample solution* (see [Ultraviolet-Visible Spectroscopy \(857\)](#)) at 310 nm.

Acceptance criteria: NMT 0.2

SPECIFIC TESTS

- **OPTICAL ROTATION, *Specific Rotation (781S)***: −10° to −12°
Sample solution: 50 mg/mL in water
- **WATER DETERMINATION, *Method I (921)***: 4.5%–5.8%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at controlled room temperature.
- **USP REFERENCE STANDARDS (11).**
[USP Norepinephrine Bitartrate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NOREPINEPHRINE BITARTRATE	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](#)

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