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Racedpinephrine Inhalation Solution

DEFINITION

Racedpinephrine Inhalation Solution is a sterile solution of Racedpinephrine in Purified Water prepared with the aid of Hydrochloric Acid, or of Racedpinephrine Hydrochloride in Purified Water. It contains NLT 90.0% and NMT 110.0% of the labeled amount of racedpinephrine ($C_9H_{13}NO_3$).

IDENTIFICATION

• A.

Sample solution: 0.5 mL of Inhalation Solution

Analysis: To 5 mL of pH 4.0 acid phthalate buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#)) add the *Sample solution* and 1.0 mL of 0.1 N iodine. Mix, and allow to stand for 5 min. Add 2 mL of sodium thiosulfate solution (1 in 40).

Acceptance criteria: A deep red color is produced.

ASSAY

• PROCEDURE

Solution A: 0.05 M monobasic sodium phosphate and methanol (85:15)

Mobile phase: 0.005 M sodium 1-octanesulfonate in *Solution A*

System suitability solution: 0.04 mg/mL of dopamine hydrochloride and 0.01 mg/mL of [USP Epinephrine Bitartrate RS](#) in *Solution A*

Standard solution: 0.1 mg/mL of [USP Epinephrine Bitartrate RS](#) in *Solution A*

Sample solution: Nominally 0.055 mg/mL of racedpinephrine prepared as follows. Transfer a suitable volume of Inhalation Solution equivalent to 11 mg of racedpinephrine to a suitable volumetric flask, and dilute with *Solution A* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

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

Suitability requirements

Resolution: NLT 5.0 between dopamine and racedpinephrine, *System suitability solution*

Tailing factor: NMT 1.2 for racedpinephrine, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of racedpinephrine ($C_9H_{13}NO_3$) in the portion of Inhalation Solution taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of racedpinephrine in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of racepinephrine, 183.20

M_{r2} = molecular weight of epinephrine bitartrate, 333.29

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **STERILITY TESTS (71):** Meets the requirements
- **pH (791):** 2.0–3.5
- **COLOR AND CLARITY**

Standard solution: Dilute 2.0 mL of 0.100 N iodine VS with water to 500 mL.

Sample solution: A portion of Inhalation Solution

Analysis: Visually examine the *Sample solution* in a suitable clear glass test tube against a white background.

Acceptance criteria: The *Sample solution* is not pinkish, and it contains no precipitate.

If any yellow color is observed in the *Sample solution*, concomitantly determine the absorbances of the *Sample solution* and the *Standard solution* in 1-cm cells with a suitable spectrophotometer set at 460 nm.

The absorbance of the *Sample solution* does not exceed that of the *Standard solution*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Do not freeze.
- **LABELING:** The label indicates that the Inhalation Solution is not to be used if its color is pinkish or darker than slightly yellow or if it contains a precipitate.

Add the following:

- ▲ **USP REFERENCE STANDARDS (11).**

[USP Epinephrine Bitartrate RS](#) ▲ (ERR 1-Aug-2018)

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

Topic/Question	Contact	Expert Committee
RACEPINEPHRINE INHALATION SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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