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## Racepinephrine Inhalation Solution

### DEFINITION

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

### 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 racepinephrine prepared as follows. Transfer a suitable volume of Inhalation Solution equivalent to 11 mg of racepinephrine 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  $\times$  25-cm; 5- $\mu$ m packing L1

**Flow rate:** 1 mL/min

**Injection volume:** 10  $\mu$ L

#### System suitability

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

#### Suitability requirements

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

**Tailing factor:** NMT 1.2 for racepinephrine, *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 racepinephrine ( $C_9H_{13}NO_3$ ) 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 racepinephrine 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	<a href="#">Documentary Standards Support</a>	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM52020 Small Molecules 5

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

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