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Racepinephrine Hydrochloride

$C_9H_{13}NO_3 \cdot HCl$ 219.67

» Racepinephrine Hydrochloride is a racemic mixture of the hydrochlorides of the enantiomorphs of epinephrine. It contains not less than 97.0 percent and not more than 102.0 percent of $C_9H_{13}NO_3 \cdot HCl$, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight, light-resistant containers.

Change to read:

USP Reference standards ⟨11⟩—

▲▲ (CN 1-May-2018)

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

USP Norepinephrine Bitartrate RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: 50 µg per mL. [Note—Use USP Epinephrine Bitartrate RS in the preparation of the *Standard solution*.]

Medium: water.

B: A solution (1 in 100) meets the requirements of the tests for *Chloride ⟨191⟩*.

Specific rotation ⟨781S⟩: between −1° and +1°.

Test solution: 10 mg per mL, in 0.12 N hydrochloric acid.

Water Determination, *Method I* ⟨921⟩: not more than 0.5%.

Residue on ignition ⟨281⟩: not more than 0.5%.

Other requirements—It meets the requirements for *Limit of adrenalone* and *Limit of norepinephrine* under *Racepinephrine*.

Assay—

Mobile phase—Prepare a filtered and degassed solution of 0.17 N acetic acid. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Epinephrine Bitartrate RS in *Mobile phase* to obtain a solution having a known concentration of about 150 µg per mL.

Assay preparation—Transfer about 25 mg of Racepinephrine Hydrochloride, accurately weighed, to a 100-mL volumetric flask. Dissolve in and dilute with *Mobile phase* to volume, and mix. Transfer 4.0 mL of this solution to a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix to obtain a solution containing about 100 µg per mL.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 278-nm detector and a 4.6-mm × 15-cm column that contains packing L1. The flow rate is about 2.0 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 25 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_9H_{13}NO_3 \cdot HCl$ in the portion of Racepinephrine Hydrochloride taken by the formula:

$$0.25C(219.67/333.30)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Epinephrine Bitartrate RS in the *Standard preparation:* 219.67 and 333.30 are the molecular weights of racepinephrine hydrochloride and epinephrine bitartrate, respectively; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
RACEPINEPHRINE HYDROCHLORIDE	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

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