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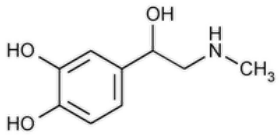
Racepinephrine



$C_9H_{13}NO_3$ 183.20

1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-, (±)-.

(±)-3,4-Dihydroxy-α-[(methylamino)methyl]benzyl alcohol CAS RN®: 329-65-7; UNII: GR0L9S3J0F.

» Racepinephrine is a racemic mixture of the enantiomorphs of epinephrine. It contains not less than 97.0 percent and not more than 102.0 percent of $C_9H_{13}NO_3$, calculated on the dried 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—To 5 mL of pH 4.0 acid phthalate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*) add 0.5 mL of a solution of Racepinephrine (1 in 1000) and 1.0 mL of 0.1 N iodine. Mix, and allow to stand for 5 minutes. Add 2 mL of sodium thiosulfate solution (1 in 40): a deep red color is produced.

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

Test solution: 10 mg per mL, in 0.6 N hydrochloric acid.

Loss on drying ⟨731⟩—Dry it in vacuum over silica gel for 18 hours: it loses not more than 2.0% of its weight.

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

Limit of adrenalone—Its absorptivity (see *Ultraviolet-Visible Spectroscopy* ⟨857⟩) at 310 nm, determined in a solution in dilute hydrochloric acid (1 in 200) containing 2 mg per mL, is not more than 0.2.

Limit of norepinephrine—

Epinephrine standard solution—Dilute with methanol an accurately measured volume of a solution of USP Epinephrine Bitartrate RS in formic acid containing about 364 mg per mL to obtain a solution having a concentration of about 20 mg per mL.

Norepinephrine standard solution—Dilute with methanol an accurately measured volume of a solution of USP Norepinephrine Bitartrate RS in formic acid containing 16 mg per mL to obtain a solution having a known concentration of 1.6 mg per mL.

Test solution—Dissolve 200 mg of Racepinephrine in 1.0 mL of formic acid, dilute with methanol to 10.0 mL, and mix.

Procedure—Apply 5-µL portions of *Epinephrine standard solution*, *Norepinephrine standard solution*, and *Test solution* to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow to dry, and develop the chromatogram in an unsaturated tank using a solvent system consisting of a mixture of *n*-butanol, water, and formic acid (7:2:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate in warm circulating air. Spray with Folin-Ciocalteu Phenol TS, followed by sodium carbonate solution (1 in 10): the R_F value of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Epinephrine standard solution*. Any spot obtained from the *Test solution* is not larger nor more intense than the spot with the same R_F value obtained from the *Norepinephrine standard solution*, corresponding to not more than 4.0% of norepinephrine.

Assay—

Ferro-citrate solution, *Buffer solution*, and *Standard preparation*—Prepare as directed under *Epinephrine Assay* ⟨391⟩.

Assay preparation—Transfer about 10 mg of Racepinephrine, accurately weighed, to a 1-liter volumetric flask. Dilute with sodium bisulfite solution (1 in 500) to volume, and mix.

Procedure—Proceed as directed for *Procedure* under *Epinephrine Assay* ⟨391⟩. Calculate the quantity, in mg, of $C_9H_{13}NO_3$ in the portion of Racepinephrine taken by the formula:

$$(183.20/333.29)C(A_U/A_S)$$

in which 183.20 and 333.29 are the molecular weights of racepinephrine and epinephrine bitartrate, respectively, C is the concentration, in µg per mL, of USP Epinephrine Bitartrate RS in the *Standard preparation,* and A_U and A_S are the absorbances of the solutions 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	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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