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Epinephrine Bitartrate Ophthalmic Solution

» Epinephrine Bitartrate Ophthalmic Solution is a sterile, buffered, aqueous solution of Epinephrine Bitartrate. It contains an amount of epinephrine bitartrate equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of epinephrine ($C_9H_{13}NO_3$). It contains a suitable antibacterial agent and may contain suitable preservatives.

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

Labeling—The label indicates that the Ophthalmic Solution is not to be used if its color is pinkish or darker than slightly yellow or if it contains a precipitate.

USP Reference standards ⟨11⟩—
USP Epinephrine Bitartrate RS

Color and clarity—Using the Ophthalmic Solution as the *Test solution*, proceed as directed for *Color and clarity* under *Epinephrine Injection*.

pH ⟨791⟩: between 3.0 and 3.8.

Other requirements—It responds to the *Identification* test under *Epinephrine Nasal Solution*, and meets the requirements under *Sterility Tests ⟨71⟩*.

Assay—

pH 2.5 Buffer—Transfer 6.8 g of monobasic potassium phosphate and 1.1 g of sodium 1-octanesulfonate to a 1-liter volumetric flask. Dissolve in water, dilute with water to volume, and mix. Adjust the solution with phosphoric acid to a pH of 2.5 ± 0.1.

Mobile phase—Prepare a filtered and degassed mixture of *pH 2.5 Buffer* and acetonitrile (850:150). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Epinephrine Bitartrate RS in water, and dilute quantitatively, and stepwise if necessary, with water to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Solution, freshly mixed and free from air bubbles, equivalent to about 50 mg of epinephrine bitartrate, to a 500-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 280-nm detector and a 3.2-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the column efficiency determined from the analyte peak is not less than 2000 theoretical plates, the tailing factor for the analyte peak is not more than 2.5, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 50 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 epinephrine ($C_9H_{13}NO_3$) in each mL of the Ophthalmic Solution taken by the formula:

$$(183.20/333.29)(500C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Epinephrine Bitartrate RS in the *Standard preparation*, V is the volume, in mL, of Ophthalmic Solution taken, 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
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Chromatographic Database Information: Chromatographic Database

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