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Epinephrine Ophthalmic Solution

» Epinephrine Ophthalmic Solution is a sterile, aqueous solution of Epinephrine prepared with the aid of Hydrochloric Acid. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_9H_{13}NO_3$. It contains a suitable antibacterial agent and may contain an anti-oxidant, suitable buffers, and chelating and tonicity-adjusting agents.

Packaging and storage—Preserve in 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](#).

Identification—

A: The UV absorption spectrum of the *Assay preparation* prepared as directed in the Assay exhibits maxima and minima at the same wavelengths as that of a similar solution of [USP Epinephrine Bitartrate RS](#).

B: A solution (1 in 2) is levorotatory.

STERILITY TESTS (71): meets the requirements.

pH (791): between 2.2 and 4.5.

Assay—

pH 5.8 Buffer—Mix 1 volume of 1 M dibasic potassium phosphate with 9 volumes of 1 M monobasic potassium phosphate. Adjust by the addition of small volumes of either solution to a pH of 5.80 ± 0.05 .

Standard preparation—Dissolve a suitable quantity of [USP Epinephrine Bitartrate RS](#), accurately weighed, in 0.1 N hydrochloric acid to obtain a solution having a known concentration of about 40 µg of epinephrine per mL.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 20 mg of epinephrine, to a 250-mL beaker containing 2.0 mL of pH 5.8 Buffer. Add 9 g of chromatographic siliceous earth, and mix. Carefully transfer the mixture to a 45- × 2.2-cm chromatographic tube containing a pledget of glass wool at the bottom, and tap the column gently to effect packing. Dry-wash the beaker with about 1 g of chromatographic siliceous earth, add to the column, and plug the top with a pledget of glass wool. Wash the column with 100 mL of water-washed ether, and discard the eluant. Add 10.0 mL of 0.1 N hydrochloric acid to a 125-mL separator, and place the separator under the column. To about 100 mL of water-washed ether add 1 mL of bis(2-ethylhexyl) phosphoric acid, and elute the column with this solution, collecting the eluate in the separator. Extract the epinephrine into the aqueous acid layer, and carefully transfer the aqueous layer to a 500-mL volumetric flask. Shake the ether layer with two 50-mL portions of 0.1 N hydrochloric acid, add the acidic aqueous extracts to the volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Assay preparation* and the *Standard preparation* at the wavelength of maximum absorbance at about 280 nm, with a suitable spectrophotometer, using 0.1 N hydrochloric acid as the blank. Calculate the quantity, in mg, of $C_9H_{13}NO_3$ in each mL of the Ophthalmic Solution taken by the formula:

$$0.5(C/V)(A_u/A_s)$$

in which *C* is the concentration, in µg per mL, of epinephrine in the *Standard preparation*; *V* is the volume, in mL, of Ophthalmic Solution taken; and *A_u* and *A_s* are the absorbances of 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
EPINEPHRINE OPHTHALMIC SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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