Phenylephrine Hydrochloride Injection

» Phenylephrine Hydrochloride Injection is a sterile solution of Phenylephrine Hydrochloride in Water for Injection. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_9H_{13}NO_2 \cdot HCl$.

Packaging and storage— Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨ 11 ⟩ —
USP Phenylephrine Hydrochloride RS.
USP Endotoxin RS.

Identification— Concentrate or dilute, if necessary, a suitable volume of Injection to a concentration of about 10 mg per mL. Apply 2 µL of this solution and of a Standard solution of *USP Phenylephrine Hydrochloride RS*, containing about 10 mg per mL, at points about 2.5 cm from the bottom edge of a suitable thin-layer chromatographic plate (see *Chromatography* ⟨ 621 ⟩) coated with a 0.25-mm layer of chromatographic silica gel. Dry the spots in a current of warm air, and develop the chromatogram in a suitable chromatographic chamber with a mixture of methanol, water, and ammonium hydroxide (72:25:3) until the solvent front has moved about 12 cm. Dry the plate in warm air, and spray it with alcoholic potassium hydroxide TS. Dry at 60° for 15 minutes, and spray the plate with *p*-nitroaniline TS: the reddish orange spot obtained from the test solution corresponds in color, size, and intensity to that obtained from the Standard solution.

Bacterial endotoxins ⟨ 85 ⟩ **—** It contains not more than 25.0 USP Endotoxin Units per mg of phenylephrine hydrochloride.

pH ⟨ 791 ⟩ : between 3.0 and 6.5.

Other requirements— It meets the requirements under *Injections* ⟨ 1 ⟩ .

Assay—

Mobile phase— Prepare and filter a mixture of methanol and water (1:1) containing 1.1 g of sodium 1-octanesulfonate per liter, adjusted with 3 M phosphoric acid to a pH of 3.0. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨ 621 ⟩).

Dilution solvent— Prepare a mixture of methanol and water (1:1), adjusted with 3 M phosphoric acid to a pH of 3.0.

System suitability solution— Dissolve about 50 mg each of *USP Phenylephrine Hydrochloride RS* and *USP Epinephrine Bitartrate RS* in 5 mL of water, dilute with *Dilution solvent* to 25.0 mL, and mix. Further dilute 5.0 mL of the resulting solution with *Dilution solvent* to 25.0 mL, and mix to obtain a solution having a concentration of about 0.4 mg of phenylephrine hydrochloride and 0.4 mg of epinephrine bitartrate per mL.

Standard preparation— Dissolve about 50 mg of *USP Phenylephrine Hydrochloride RS*, accurately weighed, in 10 mL of water, dilute with *Dilution solvent* to 25.0 mL, and mix. Further dilute 5.0 mL of the resulting solution with *Dilution solvent* to 25.0 mL, and mix to obtain a solution having a known concentration of about 0.4 mg per mL.

Assay preparation— Transfer an accurately measured volume of Injection, equivalent to about 10 mg of phenylephrine hydrochloride, to a 25-mL volumetric flask. Dilute with *Dilution solvent* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨ 621 ⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *System suitability solution*, and record the responses for the major peaks: the resolution, *R,* between epinephrine and phenylephrine is not less than 1.0. Chromatograph replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 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 $C_9H_{13}NO_2 \cdot HCl$ in each mL of the Injection taken by the formula:

$$(25C / V)(r_U / r_S)$$

in which C is the concentration, in mg per mL, of *USP Phenylephrine Hydrochloride RS* in the *Standard preparation*, V is the volume, in mL, of Injection taken, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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