Phenylephrine Hydrochloride Nasal Jelly

» Phenylephrine Hydrochloride Nasal Jelly contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_9H_{13}NO_2 \cdot HCl$.

Packaging and storage— Preserve in tight containers.

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

Identification— Dissolve a suitable quantity in water to obtain a solution having a concentration of about 60 µg per mL, and centrifuge, if necessary: the UV absorption spectrum of the solution so obtained exhibits maxima and minima at the same wavelengths as that of a similar solution of *USP Phenylephrine Hydrochloride RS*, concomitantly measured.

Minimum fill ⟨ 755 ⟩ : meets the requirements.

Assay—

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

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

Standard preparation— Dissolve an accurately weighed quantity of *USP Phenylephrine Hydrochloride RS* in *Dilution solvent* to obtain a Stock standard solution having a known concentration of about 2 mg per mL. Dilute an accurately measured volume of this solution with *Dilution solvent* to obtain the *Standard preparation* having a known concentration of about 0.1 mg per mL.

Assay preparation— Transfer an accurately weighed amount of Nasal Jelly, equivalent to about 10 mg of phenylephrine hydrochloride, to a 100-mL volumetric flask. Dilute with *Dilution solvent* to volume, and mix.

Resolution solution— Transfer 5.0 mL of Stock standard solution to a 100-mL volumetric flask, add 10 mg of *USP Epinephrine Bitartrate RS*, 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 *Resolution solution:* the resolution, *R,* is not less than 1.5, and the tailing factor for the phenylephrine peak is not more than 2.0. Chromatograph replicate injections of the *Standard preparation:* 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 the portion of Nasal Jelly taken by the formula:

$$100C(r_U / r_S)$$

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

Auxiliary Information— *Staff Liaison* : Clydewyn M. Anthony, Ph.D., Scientist
Expert Committee : (MDCCA05) Monograph Development-Cough Cold and Analgesics
USP31–NF26 Page 2987
Phone Number : 1-301-816-8139