Procedure—Proceed as directed for *Procedure* under *Single-Steroid Assay* ⟨511⟩, using a solvent system consisting of a mixture of *n*-heptane and acetone (3:1), through the fourth sentence of the second paragraph under *Procedure.* Then centrifuge the tubes for 5 minutes, and determine the absorbances of the supernatants in 1-cm cells at the wavelength of maximum absorbance at about 239 nm, with a suitable spectrophotometer, against the blank. Calculate the quantity, in mg, of $C_{27}H_{34}O_3$ in the portion of Nandrolone Phenpropionate taken by the formula:

$$10C(A_U / A_S)$$

in which C is the concentration, in mg per mL, of USP Nandrolone Phenpropionate 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.

Nandrolone Phenpropionate Injection

» Nandrolone Phenpropionate Injection is a sterile solution of Nandrolone Phenpropionate in a suitable oil. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of nandrolone phenpropionate ($C_{27}H_{34}O_3$).

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

USP Reference standards ⟨11⟩**—**
USP Nandrolone RS

Identification—Dilute the Injection with acetone to obtain a solution containing 5 mg of nandrolone phenpropionate in each mL. Proceed as directed for *Identification* test *C* under *Nandrolone Phenpropionate*, beginning with "Apply 10 µL of this solution."

Limit of nandrolone—

Standard preparation—Prepare as directed in the test for *Limit of nandrolone* under *Nandrolone Decanoate Injection*.

Test preparation—Transfer an accurately measured volume of Injection, equivalent to about 50 mg of nandrolone phenpropionate, to a 10-mL volumetric flask, dilute with acetone to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the test for *Limit of nandrolone* under *Nandrolone Decanoate Injection*.

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

Assay—

Isoniazid reagent—Dissolve 500 mg of isoniazid in about 250 mL of methanol, add 0.63 mL of hydrochloric acid, dilute with methanol to 500.0 mL, and mix.

Standard preparation—Transfer about 25 mg of USP Nandrolone Phenpropionate RS, accurately weighed, to a 100-mL volumetric flask, dissolve in chloroform, dilute with chloroform to volume, and mix. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, dilute with chloroform to volume, and mix.

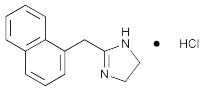
Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 50 mg of nandrolone phenpropionate, to a 200-mL volumetric flask, dilute with chloroform to volume, and mix. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, dilute with chloroform to volume, and mix.

Procedure—Transfer 5.0 mL each of the *Standard preparation*, of the *Assay preparation*, and of chloroform to provide the blank, to separate 10-mL volumetric flasks, dilute each flask with *Isoniazid reagent* to volume, and mix. Allow the flasks to stand for 1 hour with occasional shaking. Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 380 nm, with a suitable spectrophotometer, against the blank. Calculate the quantity, in mg, of $C_{27}H_{34}O_3$ in each mL of the Injection taken by the formula:

$$(2C / V)(A_U / A_S)$$

in which C is the concentration, in µg per mL, of USP Nandrolone Phenpropionate RS in the *Standard preparation*, V is the volume, in mL, of Injection taken, and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

Naphazoline Hydrochloride



$C_{14}H_{14}N_2 \cdot HCl$ 246.74
1*H*-Imidazole, 4,5-dihydro-2-(1-naphthalenylmethyl)-, monohydrochloride.
2-(1-Naphthylmethyl)-2-imidazoline monohydrochloride [550-99-2].

» Naphazoline Hydrochloride contains not less than 98.0 percent and not more than 102.0 percent of $C_{14}H_{14}N_2 \cdot HCl$, calculated on the dried basis.

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

USP Reference standards ⟨11⟩**—**
USP Naphazoline Hydrochloride RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 20 µg per mL.

Medium: methanol.

Absorptivities at 280 nm, calculated on the dried basis, do not differ by more than 3.0%.

C: A solution (1 in 100) responds to the tests for *Chloride* ⟨191⟩.

pH ⟨791⟩**:** between 5.0 and 6.6, in a 1 in 100 solution in carbon dioxide-free water, and the solution is clear and colorless.

Loss on drying ⟨731⟩**—**Dry it at 105° for 2 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.2%.

Ordinary impurities ⟨466⟩**—**

Test solution: methanol.

Standard solution: methanol.

Eluant: a mixture of methanol, glacial acetic acid, and water (8:1:1).

Visualization: 2.

Assay—

Buffer—In a 1000-mL volumetric flask, dissolve 3.0 g of monobasic potassium phosphate, accurately weighed, in 800 mL of water. Add 3.0 mL of triethylamine, adjust with phosphoric acid to a pH of 3.0, dilute with water to volume, and mix.

Mobile phase—Prepare a filtered and degassed solution of *Buffer* and acetonitrile (80:20). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Naphazoline Hydrochloride RS in water, and dilute

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quantitatively, and stepwise if necessary, to obtain a concentration of 0.05 mg per mL.

Assay preparation—Transfer about 200 mg of Naphazoline Hydrochloride, accurately weighed, to a 200-mL volumetric flask, and dissolve in and dilute with water to volume. Transfer 5.0 mL of this solution to a 100-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 4.0-mm × 25-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the capacity factor, *k′,* is not less than 2.0; the column efficiency is not less than 1500 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections of the *Standard preparation* 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 $C_{14}H_{14}N_2 \cdot HCl$ in the portion of Naphazoline Hydrochloride taken by the formula:

$$4000C(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Naphazoline 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.

Naphazoline Hydrochloride Nasal Solution

» Naphazoline Hydrochloride Nasal Solution is a solution of Naphazoline Hydrochloride in water adjusted to a suitable pH and tonicity. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of naphazoline hydrochloride ($C_{14}H_{14}N_2 \cdot HCl$).

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

USP Reference standards ⟨11⟩**—**
USP Naphazoline Hydrochloride RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* as obtained in the *Assay*.

Assay—

Mobile phase—Dissolve 1.1 g of sodium 1-heptanesulfonate in about 400 mL of water. Add 250 mL of acetonitrile and 10 mL of glacial acetic acid, dilute with water to 1000 mL, and mix. Sonicate for 10 minutes, filter, and degas to obtain a solution having a pH of about 3.5. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Naphazoline Hydrochloride RS in water, and dilute quantitatively, and stepwise if necessary, with water to obtain a solution having a known concentration of about 250 µg per mL.

Assay preparation—Pipet a volume of Nasal Solution, equivalent to about 25 mg of naphazoline hydrochloride, into a 100-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 4-mm × 30-cm column that contains packing L11. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed under *Procedure:* the tailing factor for the naphazoline hydrochloride peak is not more than 2.0, and the relative standard deviation for replicate injections is not more than 1.5%.

Procedure—Separately inject equal volumes (about 15 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 $C_{14}H_{14}N_2 \cdot HCl$ in each mL of the Nasal Solution taken by the formula:

$$0.1(C / V)(r_U / r_S)$$

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

Naphazoline Hydrochloride Ophthalmic Solution

» Naphazoline Hydrochloride Ophthalmic Solution is a sterile, buffered solution of Naphazoline Hydrochloride in water adjusted to a suitable tonicity. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of naphazoline hydrochloride ($C_{14}H_{14}N_2 \cdot HCl$). It contains a suitable preservative.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Naphazoline Hydrochloride RS

Identification—Place in a separator a volume of Ophthalmic Solution, equivalent to about 25 mg of naphazoline hydrochloride, add 5 mL of 1 N sodium hydroxide, saturate with sodium chloride, and extract with two 25-mL portions of ether. Wash the ether solution with 5 mL of water, pass the ether through a small paper filter, evaporate the filtrate to about 5 mL, transfer the residual solution to a 10- to 15-mL beaker, allow to evaporate spontaneously, and dry the residue at 80° for 1 hour: the naphazoline so obtained melts between 115° and 120° when determined as directed for *Class Ia* under *Melting Range or Temperature* ⟨741⟩.

Sterility ⟨71⟩**:** meets the requirements.

pH ⟨791⟩: between 5.5 and 7.0.

Assay—

Phosphate buffer—Transfer 3 g of monobasic potassium phosphate to a 1-L volumetric flask, dissolve in 1000 mL of water and 3 mL of triethylamine, and mix. Adjust with phosphoric acid to a pH of 3, and mix.

Mobile phase—Prepare a filtered and degassed mixture of *Phosphate buffer* and acetonitrile (80:20). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Naphazoline Hydrochloride RS in water, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.05 mg per mL.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 5.0 mg of naphazoline hydrochloride, to a 100-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 285-nm detector and a 4.6-mm × 15-cm column that contains packing L10. The flow rate is about 1.5 mL per minute. The column temperature is maintained at 40°. Chromatograph the *Standard preparation,*

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