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Tetrahydrozoline Hydrochloride Nasal Solution

» Tetrahydrozoline Hydrochloride Nasal Solution is a solution of Tetrahydrozoline Hydrochloride in water adjusted to a suitable tonicity. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{13}H_{16}N_2 \cdot HCl$.

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)—

[USP Tetrahydrozoline Hydrochloride RS](#)

Identification—The UV absorption spectrum of the Nasal Solution, diluted with water, if necessary, to a concentration of about 1 in 4000, exhibits maxima and minima at the same wavelengths as that of a similar solution of [USP Tetrahydrozoline Hydrochloride RS](#), concomitantly measured.

MICROBIAL ENUMERATION TESTS (61) and TESTS FOR SPECIFIED MICROORGANISMS (62)—It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

pH (791): between 5.3 and 6.5.

Assay—

Oxidized nitroprusside reagent—Dissolve 1.0 g of sodium nitroferricyanide in water to make 10.0 mL (*Solution A*). Dissolve 1.0 g of potassium ferricyanide in water to make 10.0 mL (*Solution B*). Transfer 1.0 mL each of *Solution A* and *Solution B* to a 100-mL volumetric flask, add 1 mL of sodium hydroxide solution (1 in 10), and allow to stand until the solution changes to a light yellow color (about 20 to 30 minutes). Dilute with water to volume, and mix. Store in a refrigerator or keep in an ice bath, and use within 4 hours.

Standard preparation—Dissolve a suitable quantity of [USP Tetrahydrozoline Hydrochloride RS](#), accurately weighed, in water, and dilute quantitatively with water to obtain a solution having a known concentration of about 100 μ g per mL.

Assay preparation—Transfer an accurately measured volume of Nasal Solution, equivalent to about 10 mg of tetrahydrozoline hydrochloride, to a 100-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Transfer 5.0 mL each of the *Standard preparation* and the *Assay preparation* to separate glass-stoppered test tubes. Pipet 5 mL of water into a third tube to provide a blank. To each tube add 4.0 mL of *Oxidized nitroprusside reagent*, mix, and allow to stand at 30° for 15 minutes. Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 570 nm, with a suitable spectrophotometer, using the blank to set the instrument. Calculate the quantity, in mg, of $C_{13}H_{16}N_2 \cdot HCl$ in each mL of the Nasal Solution taken by the formula:

$$0.1(C/V)(A_u/A_s)$$

in which *C* is the concentration, in μ g per mL, of [USP Tetrahydrozoline Hydrochloride RS](#) in the *Standard preparation*, *V* is the volume, in mL, of Nasal Solution taken, and A_u and A_s are the absorbances of the solutions 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
TETRAHYDROZOLINE HYDROCHLORIDE NASAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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