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Proparacaine Hydrochloride Ophthalmic Solution

DEFINITION

Proparacaine Hydrochloride Ophthalmic Solution is a sterile, aqueous solution of Proparacaine Hydrochloride. It contains NLT 95.0% and NMT 110.0% of the labeled amount of proparacaine hydrochloride ($C_{16}H_{26}N_2O_3 \cdot HCl$).

IDENTIFICATION

• **A.**

Solution A: Dilute hydrochloric acid (1 in 100)

Solution B: 100 mg/mL of sodium nitrite

Solution C: 20 mg/mL of 2-naphthol in 1 N sodium hydroxide

Sample solution: 1 mL of Ophthalmic Solution

Analysis 1: To the *Sample solution* in a test tube add 5 mL of *Solution A*, mix, and cool in an ice bath for 2 min. Add 2 drops of *Solution B*, stir, and cool again for 2 min. Add 1 mL of *Solution C*.

Acceptance criteria 1: A scarlet-red precipitate is formed.

Analysis 2: Add 5 mL of acetone to the test tube contents of *Analysis 1*.

Acceptance criteria 2: The precipitate does not dissolve.

ASSAY

• **Procedure**

Buffer: 6.8 g/L of monobasic potassium phosphate. Add 5 mL of triethylamine, and adjust with 5 N potassium hydroxide to a pH of 7.5. Pass through a filter of 0.5-µm or finer pore size, and degas.

Mobile phase: Acetonitrile and *Buffer* (40:60)

Standard stock solution: 1 mg/mL of USP Proparacaine Hydrochloride RS

Standard solution: 0.1 mg/mL of USP Proparacaine Hydrochloride RS in *Mobile phase* from the *Standard stock solution*. Use this solution within 6 h.

Sample solution: Nominally equivalent to 0.1 mg/mL of proparacaine hydrochloride from a measured volume of Ophthalmic Solution in *Mobile phase*. Use this solution within 6 h.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 15-cm; 5-µm spherical packing L10

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 3000 theoretical plates

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of proparacaine hydrochloride ($C_{16}H_{26}N_2O_3 \cdot HCl$) in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of USP Proparacaine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of proparacaine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–110.0%

SPECIFIC TESTS

- **Sterility Tests ⟨71⟩:** Meets the requirements
- **pH ⟨791⟩:** 3.5–6.0

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **Labeling:** Label it to indicate that it is to be stored in a refrigerator after the container is opened.
- **USP Reference Standards ⟨11⟩**
  USP Proparacaine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PROPARACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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