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Lidocaine, Racepinephrine, and Tetracaine Hydrochlorides Compounded Topical Gel

Change to read:

DEFINITION

Lidocaine, Racepinephrine, and Tetracaine Hydrochlorides Compounded Topical Gel, contains NLT 90.0% and NMT 110.0% of the labeled amount of lidocaine hydrochloride ($C_{14}H_{22}N_2O \cdot HCl$), racepinephrine hydrochloride ($C_9H_{13}NO_3 \cdot HCl$), and tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$).

Prepare Lidocaine, Racepinephrine, and Tetracaine Hydrochlorides Compounded Topical Gel containing 40 mg/mL of lidocaine hydrochloride, 1 mg/mL of racepinephrine hydrochloride, and 10 mg/mL of tetracaine hydrochloride as follows (see ▲*Pharmaceutical Compounding—Nonsterile Preparations (795)*▲ (ERR 1-Apr-2024)). For this preparation, a *Paraben Solution* needs to be separately prepared.

Methylparaben	50 mg
Propylparaben	25 mg
Purified Water, a sufficient quantity to make	100 mL

Prepare a *Paraben Solution* by dissolving the *Methylparaben* and *Propylparaben* in a sufficient amount of *Purified Water* to bring to final volume.

Lidocaine Hydrochloride powder	4 g
Racepinephrine Hydrochloride powder	0.1 g
Tetracaine Hydrochloride powder	1 g
Sodium Bisulfite powder	300 mg
Hydroxyethyl Cellulose 5000	2 g
Paraben Solution, a sufficient quantity to make	100 mL

[Note—Racepinephrine Hydrochloride is a racemic mixture of the hydrochlorides of the enantiomorphs of epinephrine.]

Dissolve the *Lidocaine Hydrochloride*, *Racepinephrine Hydrochloride*, *Tetracaine Hydrochloride*, and *Sodium Bisulfite* powder in 75 mL of the *Paraben Solution*. Add sufficient *Paraben Solution* to bring to final volume and mix well.

Protect from light by covering with aluminum foil. Sprinkle in the *Hydroxyethyl Cellulose 5000* through a strainer. Cover the container and stir with a stir bar. Allow to sit until a clear homogenous gel is formed. Slowly stir to avoid introducing air into the gel.

ASSAY

• **Procedure**

Solution A: 0.23% (v/v) trifluoroacetic acid in water

Mobile phase: See *Table 1*.

Table 1

Time (min)	Acetonitrile (%)	Solution A (%)
0	1	99
5	1	99

Time (min)	Acetonitrile (%)	Solution A (%)
30	75	25
31	1	99
40	1	99

Standard solution: 0.2 mg/mL of lidocaine hydrochloride, 0.04 mg/mL of racepinephrine hydrochloride, and 0.05 mg/mL of tetracaine hydrochloride from USP Lidocaine Hydrochloride RS, USP Racepinephrine Hydrochloride RS, and USP Tetracaine Hydrochloride RS in water. [NOTE—*Standard solution* must be prepared fresh daily.]

Sample solution

For Lidocaine Hydrochloride and Tetracaine Hydrochloride: Add approximately 20 mL of water to a 200-mL volumetric flask. Transfer 1.0 mL of Topical Gel into the volumetric flask and mix well. Dilute with water to final volume. [NOTE—*Sample solution* for Tetracaine Hydrochloride must be prepared fresh daily.]

For Racepinephrine Hydrochloride: Add approximately 20 mL of water to a 250-mL volumetric flask. Transfer 10 mL of Topical Gel into the volumetric flask and mix well. Dilute with water to final volume.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Temperatures

Autosampler: 4°

Column: 30°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention times for lidocaine hydrochloride, racepinephrine hydrochloride, and tetracaine hydrochloride are about 17.8, 6.2, and 21.4 min, respectively.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lidocaine hydrochloride ($C_{14}H_{22}N_2O \cdot HCl$) in the portion of Topical Gel:

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

r_U = peak response of lidocaine hydrochloride from the *Sample solution*

r_S = peak response of lidocaine hydrochloride from the *Standard solution*

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

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

Calculate the percentage of the labeled amount of racepinephrine hydrochloride ($C_9H_{13}NO_3 \cdot HCl$) in the portion of Topical Gel:

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

r_U = peak response of racepinephrine hydrochloride from the *Sample solution*

r_S = peak response of racepinephrine hydrochloride from the *Standard solution*

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

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

Calculate the percentage of the labeled amount of tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$) in the portion of Topical Gel:

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

r_U = peak response of tetracaine hydrochloride from the *Sample solution*

r_S = peak response of tetracaine hydrochloride from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0% for each compound

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.2–4.2

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in a tight, light-resistant suitable calibrated single-use container. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 60 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator.

• **Labeling:** Label it to state the *Beyond-Use Date*. Label it to indicate that it is for external use only. Label it to indicate that it is not to be used if its color is pinkish or darker than slightly yellow or if it contains a precipitate.

• **USP Reference Standards** ⟨11⟩

USP Lidocaine Hydrochloride RS
USP Racepinephrine Hydrochloride RS
USP Tetracaine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
LIDOCAINE, RACEPINEPHRINE AND TETRACAINE HYDROCHLORIDES COMPOUNDED TOPICAL GEL	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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