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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

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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:

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

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