Acceptance criteria: The *Sample solution* is considered clear if its clarity is the same as that of water or if its opalescence is not more pronounced than that of *Standard suspension 1*.

- **pH** ⟨**791**⟩**:** 4.5–6.0, in a solution (10 mg/mL)
- **Water Determination,** *Method Ia* ⟨**921**⟩**:** 5.0%–6.0%. Perform the determination on 0.0900–0.1100 g of sample.
- **Sterility Tests** ⟨**71**⟩**:** Where the label states that Ropivacaine Hydrochloride is sterile, it meets the requirements.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Store at room temperature.
- **Labeling:** Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.
- **USP Reference Standards** ⟨**11**⟩
  USP Bupivacaine Hydrochloride RS
  USP Endotoxin RS
  USP Ropivacaine Hydrochloride RS
  USP Ropivacaine Related Compound A RS
  2,6-Dimethylaniline hydrochloride.
  $C_8H_{12}ClN$ 157.64 [CAS-21436-98-6]
  USP Ropivacaine Related Compound B RS
  (R)-ropivacaine hydrochloride monohydrate; *(R)*-(–)-1-propylpiperidene-2-carboxylic acid (2,6-dimethylphenyl)-amide hydrochloride monohydrate.
  $C_{17}H_{26}N_2O$ 328.89

Ropivacaine Hydrochloride Injection

» Ropivacaine Hydrochloride Injection is a sterile solution of Ropivacaine Hydrochloride in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ropivacaine hydrochloride ($C_{17}H_{26}N_2O \cdot HCl$).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type 1 glass or of suitable plastic.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS
USP Ropivacaine Hydrochloride RS
USP Ropivacaine Related Compound A RS
2,6-Dimethylaniline hydrochloride.
$C_8H_{12}ClN$ 157.64 [CAS-21436-98-6].
USP Ropivacaine Related Compound B RS
(R)-ropivacaine hydrochloride monohydrate; *(R)*-(–)-1-propylpiperidene-2-carboxylic acid (2,6-dimethylphenyl)-amide hydrochloride monohydrate.
$C_{17}H_{26}N_2O$ 328.89

Identification—

A: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

B: The retention time of the major peak in the chromatogram of the *Test solution* corresponds to that in the chromatogram of the *System suitability solution,* as obtained in the test for *Enantiomeric purity*.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 60 USP Endotoxin Units per g of ropivacaine hydrochloride.

Particulate matter ⟨788⟩**:** meets the requirements for injections.

Sterility ⟨71⟩**—**It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩**:** between 4.0 and 6.0.

Limit of 2,6-dimethylaniline (ropivacaine related compound A, base)—

pH 8.0 Buffer solution and *Mobile phase*—Prepare as directed in the *Assay*.

Standard solution—Prepare as directed for *Standard preparation* in the *Assay*.

Test solution—Dilute accurately the Injection with *Mobile phase* to obtain a concentration of 2.0 mg per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 240-nm detector and a 3.9-mm × 15-cm column that contains 5-µm packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between ropivacaine related compound A and ropivacaine is not less than 5; and the signal-to-noise ratio for ropivacaine related compound A is not less than 10.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. The peak response of ropivacaine related compound A obtained from the *Test solution* is not greater than the corresponding response obtained from the *Standard solution* (not more than 0.01% of ropivacaine related compound A base is found).

Enantiomeric purity—

pH 7.2 Buffer solution—Transfer 7.5 mL of 1 M monobasic sodium phosphate solution and 28.5 mL of 0.5 M dibasic sodium phosphate dihydrate solution into a 1-L volumetric flask, and dilute with water to volume. Adjust the resulting solution to a pH of 7.2, if necessary.

Mobile phase—Transfer 35 mL of isopropyl alcohol into a 500-mL volumetric flask, dilute with *pH 7.2 Buffer solution* to volume, mix, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

System suitability solution—Dissolve suitable quantities of USP Ropivacaine Hydrochloride RS and USP Ropivacaine Related Compound B RS in water, and dilute quantitatively, and stepwise, with water to obtain a solution containing about 75 µg per mL and 0.75 µg per mL, respectively.

Test solution—Dilute the Injection with *Mobile phase* to a concentration of about 75 µg per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 220-nm detector and a 4-mm × 10-cm column that contains packing L41. The flow rate is about 1 mL per minute. Chromatograph the *System suitability solution,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between ropivacaine related compound B (*R* enantiomer) and ropivacaine (*S* enantiomer) is not less than 1.5. [NOTE—For the purpose of identification, the relative retention times are about 0.75 for ropivacaine related compound B and 1.0 for ropivacaine.]

Procedure—Inject about 20 µL of the *Test solution* into the chromatograph, record the chromatogram, and measure the peak responses. Calculate the percentage of ropivacaine related compound B (*R* enantiomer) in the portion of Injection taken by the formula:

$$100(r_i / r_s)$$

in which r_i is the peak response of ropivacaine related compound B (*R* enantiomer); and r_s is the sum of the peak responses of ropivacaine (*S* enantiomer) and ropivacaine related compound B (*R* enantiomer) obtained from the *Test solution:* not more than 2.0% of ropivacaine related compound B (*R* enantiomer) is found.

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

Assay—

pH 8.0 Buffer solution—Transfer 1.3 mL of 1 M monobasic sodium phosphate solution and 32.5 mL of 0.5 M dibasic sodium phosphate dihydrate solution to a 1-L volumetric flask. Dilute with water to volume, and mix. Adjust the resulting solution to a pH of 8.0, if necessary.

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile and *pH 8.0 Buffer solution* (60:40). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve accurately weighed quantities of USP Ropivacaine Hydrochloride RS and USP Ropivacaine Related Compound A RS in *Mobile phase,* and dilute quantitatively, and stepwise, with *Mobile phase* to obtain a solution having known concentrations of about 0.25 mg per mL of USP Ropivacaine Hydrochloride RS and about 0.26 µg per mL of USP Ropivacaine Related Compound A RS.

Assay preparation—Dilute accurately the Injection with *Mobile phase* to obtain a concentration of about 0.25 mg per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 240-nm detector and a 3.9-mm × 15-cm column that contains 5- or 10-µm packing L1. The flow rate is about 1.2 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections, calculated for the ropivacaine peak, is not more than 1.0%; and the resolution, *R,* between ropivacaine related compound A and ropivacaine is not less than 5.

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 ropivacaine hydrochloride ($C_{17}H_{26}N_2O \cdot HCl$) in each mL of Injection taken by the formula:

$$CD(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Ropivacaine Hydrochloride RS in the *Standard preparation; D* is the dilution factor, in mL, for the *Assay preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Rose Water Ointment

» Prepare Rose Water Ointment as follows:

Cetyl Esters Wax	125 g
White Wax	120 g
Almond Oil	560 g
Sodium Borate	5 g
Stronger Rose Water	25 mL
Purified Water	165 mL
Rose Oil	200 µL
To make about	1000 g

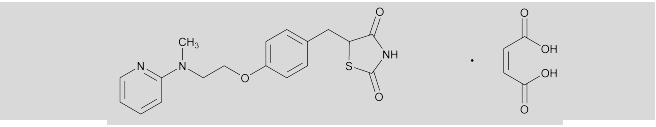
Reduce the cetyl esters wax and the white wax to small pieces, melt them on a steam bath, add the almond oil, and continue heating until the temperature of the mixture reaches 70°. Dissolve the sodium borate in the purified water and the stronger rose water, warmed to 70°, and gradually add the warm aqueous phase to the melted oil phase, stirring rapidly and continuously until it has cooled to about 45°. Then incorporate the rose oil.

NOTE—Rose Water Ointment is free from rancidity. If the Ointment has been chilled, warm it slightly before attempting to incorporate other ingredients (see *Ointments and Suppositories* in the section *Added Substances* under *Ingredients and Processes* in the *General Notices*).

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

Add the following:

▲Rosiglitazone Maleate



$C_{18}H_{19}N_3O_3S \cdot C_4H_4O_4$ 473.50

(±)-5-[*p*-[2-(Methyl-2-pyridylamino)ethoxy]benzyl]-2,4-thiazolidinedione maleate (1:1);
(*RS*)-5-{[4-({2-[Methyl(2-pyridinyl)amino]ethyl}oxy)-phenyl]methyl}-1,3-thiazolidine-2,4-dione (*Z*)-2-butenedioate [155141-29-0].

DEFINITION

Rosiglitazone Maleate contains NLT 98.0% and NMT 102.0% of $C_{18}H_{19}N_3O_3S \cdot C_4H_4O_4$, calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

- **A. Infrared Absorption** ⟨197M⟩
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution,* as obtained in the *Assay*.

ASSAY

- **Procedure**

Buffer: Dissolve 5.75 g of phosphoric acid in 800 mL water, adjust with 4 N sodium hydroxide to a pH of 3.0, and dilute with water to 1 L.

Mobile phase: Acetonitrile and *Buffer* (25:75)

System suitability solution: Transfer 2.5 mg of USP Rosiglitazone Maleate RS and 1 mg of USP Rosiglitazone Related Compound A RS to a 50-mL volumetric flask, dissolve in 1 mL of stabilizer-free tetrahydofuran, and dilute with *Mobile phase* to volume.

Standard solution: 0.05 mg/mL of USP Rosiglitazone Maleate RS in *Mobile phase*

Sample solution: 0.05 mg/mL of Rosiglitazone Maleate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

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

Column temperature: 40°

Flow rate: 1 mL/min

Injection size: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: Greater than 2.0 between rosiglitazone and rosiglitazone related compound A, *System suitability solution*