phase to volume, and mix. Pass a 10-mL portion of the solution through a filter having a 0.45-µm or finer porosity, discarding the first 4 mL of the filtrate.

Procedure—Proceed as directed in the *Compliance assay for suppositories compounded in fatty acid base.* Calculate the quantity, in mg, of morphine sulfate pentahydrate [$(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O$] in the Suppository taken by the formula:

$$(758.83/668.77)(100C)(r_U / r_S)$$

in which the terms are as defined therein.

Morrhuate Sodium Injection

» Morrhuate Sodium Injection is a sterile solution of the sodium salts of the fatty acids of Cod Liver Oil. It contains, in each mL, not less than 46.5 mg and not more than 53.5 mg of morrhuate sodium. A suitable antimicrobial agent, not to exceed 0.5 percent, and ethyl alcohol or benzyl alcohol, not to exceed 3.0 percent, may be added. NOTE—Morrhuate Sodium Injection may show a separation of solid matter on standing. Do not use the material if such solid does not dissolve completely upon warming.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass. It may be packaged in 50-mL multiple-dose containers.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS

Identification—Evaporate about 5 mL of the chloroform solution of the fatty acids obtained in the test for *Iodine value of the fatty acids* on a steam bath nearly to dryness, dissolve the residue in 1 mL of chloroform, and add 1 drop of sulfuric acid: a transient red color is produced, and it changes to brown-red.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 1.4 USP Endotoxin Units per mg of morrhuate sodium.

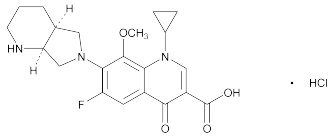
Acidity and alkalinity—To 5 mL of Injection add 5 mL of alcohol and 2 drops of phenolphthalein TS. If no red color is produced, not more than 0.50 mL of 0.10 N sodium hydroxide is required to impart a distinct red color. If a red color is produced, not more than 0.30 mL of 0.10 N acid is required to discharge it. For concentrations of morrhuate sodium other than 5%, no larger than proportional volumes of alkali and acid are required.

Iodine value of the fatty acids—Transfer to a tared, 125-mL conical flask the solvent hexane solution of the fatty acids obtained in the *Assay*. Evaporate at about 60° to dryness, dry the residue in vacuum over silica gel for 18 hours, and weigh. Dissolve the residue in chloroform to make 100.0 mL of solution, and determine the iodine value (see *Fats and Fixed Oils* ⟨401⟩) on a 25.0-mL aliquot of the solution: the iodine value is not less than 130.

Other requirements—It meets the requirements under *Injections* ⟨1⟩, except that at times it may show a slight turbidity or precipitate.

Assay—Transfer an accurately measured volume of Injection, equivalent to about 500 mg of morrhuate sodium, to a small separator containing 30.0 mL of 0.1 N sulfuric acid VS, add 25 mL of solvent hexane, shake gently, and allow to separate. Withdraw the aqueous layer into a beaker or flask, and wash the solvent hexane layer with two 10-mL portions of water, adding the washings to the main aqueous solution. Retain the hexane solution for the test for *Iodine value of the fatty acids*. Add methyl orange TS, and titrate the excess acid in the aqueous solution with 0.1 N sodium hydroxide VS. Each mL of 0.1 N sulfuric acid is equivalent to 32.4 mg of morrhuate sodium.

Moxifloxacin Hydrochloride



$C_{21}H_{24}FN_3O_4 \cdot HCl$ 437.89
(4a*S*-*cis*)-1-Cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-(octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl)-4-oxo-3-quinolinecarboxylic acid, monohydrochloride.
1-Cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid, monohydrochloride [186826-86-8].

» Moxifloxacin Hydrochloride contains not less than 98.0 percent and not more than 102.0 percent of $C_{21}H_{24}FN_3O_4 \cdot HCl$, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight, light-resistant containers. Store at room temperature.

USP Reference standards ⟨11⟩**—**
USP Moxifloxacin Hydrochloride RS
USP Moxifloxacin Related Compound A RS
1-Cyclopropyl-6,8-difluoro-1,4-dihydro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid.
$C_{20}H_{21}F_2N_3O_3$ 389.40

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: 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*.

C: To a solution (1 in 160) add diluted nitric acid, and filter. The filtrate meets the requirements of the tests for *Chloride* ⟨191⟩.

Specific rotation ⟨781S⟩: between –125° and –138° at 20°.

Test solution: 10 mg per mL, in a mixture of water and acetonitrile (1:1).

Microbial enumeration tests ⟨61⟩ and **Tests for specified microorganisms** ⟨62⟩**—**The total aerobic microbial count does not exceed 1000 cfu per g, and the total combined molds and yeasts count does not exceed 100 cfu per g.

pH ⟨791⟩: between 3.9 and 4.6, in a solution (0.2 in 100).

Water, *Method Ia* ⟨921⟩: not more than 4.5%.

Residue on ignition ⟨281⟩: not more than 0.1%.

Sulfate ⟨221⟩**—**A 0.6-g portion shows no more sulfate than corresponds to 0.25 mL of 0.020 N sulfuric acid (0.04%).

Related compounds—[NOTE—Protect solutions from light.]

Mobile phase and *Diluent*—Prepare as directed in the *Assay.*

Blank solution—Use the *Diluent.*

Resolution solution—Prepare as directed in the *Assay.*

Sensitivity solution—Dilute an accurately measured volume of the *Standard solution* with *Diluent* to obtain a solution containing about 0.05 µg per mL. [NOTE—Store the *Sensitivity solution* under refrigeration and protected from light.]

Standard solution—Dissolve an accurately weighed quantity of USP Moxifloxacin Hydrochloride RS in *Diluent,* and dilute quantitatively, and stepwise if necessary, with *Diluent* to obtain a solution having a known concentration of about 0.002 mg per mL.

Test solution—Use the *Assay preparation.*

Chromatographic system (see *Chromatography* ⟨621⟩)—Prepare the *Chromatographic system* as directed in the *Assay.* Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between moxifloxacin and moxifloxacin related compound A is not less than 1.5. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the column efficiency using the moxifloxacin peak is not less than 4000 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%. In addition, chromatograph the *Sensitivity solution,* and record the peak response as directed for *Procedure.* Confirm that the signal-to-noise ratio of the moxifloxacin peak is not less than 10.

Procedure—Separately inject equal volumes (about 25 µL) of the *Blank solution,* the *Standard solution,* and the *Test solution* into the chromatograph, record the chromatograms for at least 2 times the retention time of moxifloxacin, and measure the peak responses, disregarding any peaks corresponding to those obtained from the *Blank solution.* Calculate the percentage of each impurity in the portion of Moxifloxacin Hydrochloride taken by the formula:

$$(C_S / C_U)(1/F)(100)(r_i / r_S)$$

in which C_S is the concentration, in mg per mL, of USP Moxifloxacin Hydrochloride RS in the *Standard solution;* C_U is the concentration, in mg per mL, of Moxifloxacin Hydrochloride in the *Test solution; F* is the relative response factor for the individual related compound; r_i is the peak response of each individual impurity; r_S is the peak response of moxifloxacin in the *Standard solution;* and 100 is the conversion factor to percentage. The limits as shown in *Table 1* are met.

Table 1

Related Compound	*F*	Relative Retention Time vs. Moxifloxacin	Limit (%)
Moxifloxacin related compound A[1]	1.0	1.15	0.1
6,8-Dimethoxy[2]	0.71	1.32	0.1
8-Ethoxy[3]	1.0	1.48	0.1
6-Methoxy-8-fluoro[4]	1.0	1.71	0.1
8-Hydroxy[5]	0.29	1.83	0.1
Other individual impurity	1.0	—	0.1
Total impurities	—	—	0.5

[1]1-Cyclopropyl-6,8-difluoro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

[2]1-Cyclopropyl-6,8-dimethoxy-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

[3]1-Cyclopropyl-8-ethoxy-6-fluoro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

[4] 1-Cyclopropyl-8-fluoro-6-methoxy-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

[5]1-Cyclopropyl-6-fluoro-8-hydroxy-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

Assay—

Buffer solution—Dissolve 0.5 g of tetrabutylammonium hydrogen sulfate and 1.0 g of monobasic potassium phosphate in water, add 2 mL of phosphoric acid, dilute with water to 1000 mL, mix, and pass through a 0.45-µm filter.

Mobile phase—Prepare a degassed mixture of *Buffer solution* and methanol (18:7). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluent—Add 20 mg of anhydrous sodium sulfite to 1000 mL of *Buffer solution*, mix gently, and pass through a 0.45-µm filter.

Resolution solution—Dissolve suitable quantities of USP Moxifloxacin Hydrochloride RS and USP Moxifloxacin Related Compound A RS in *Diluent* to obtain a solution containing about 0.1 mg per mL and 0.001 mg per mL, respectively.

Standard preparation—Dissolve an accurately weighed quantity of USP Moxifloxacin Hydrochloride RS in *Diluent,* and dilute quantitatively, and stepwise if necessary, with *Diluent* to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Transfer about 50 mg of Moxifloxacin Hydrochloride, accurately weighed, to a 10-mL volumetric flask, dissolve in and dilute with *Diluent* to volume, and mix. Transfer 1.0 mL of this solution to a 50-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 293-nm detector and 4.0-mm × 25-cm column that contains 5-µm packing L11. The flow rate is about 0.9 mL per minute. The column temperature is maintained at 45°. Chromatograph the *Resolution solution* as directed for *Procedure,* and identify the components based on their relative retention times (about 1.0 for moxifloxacin and 1.2 for moxifloxacin related compound A). The resolution, *R,* between moxifloxacin and moxifloxacin related compound A is not less than 1.5. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the column efficiency using the moxifloxacin peak is not less than 4000 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 25 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 percentage of $C_{21}H_{24}FN_3O_4 \cdot HCl$ in the portion of Moxifloxacin Hydrochloride taken by the formula:

$$100(C_S / C_U)(r_U / r_S)$$

in which 100 is the conversion factor to percentage; C_S is the concentration, in mg per mL, of USP Moxifloxacin Hydrochloride RS in the *Standard preparation;* C_U is the concentration, in mg per mL, of Moxifloxacin Hydrochloride in the *Assay preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Moxifloxacin Ophthalmic Solution

» Moxifloxacin Ophthalmic Solution is a sterile, self-preserved aqueous solution of Moxifloxacin Hydrochloride. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of moxifloxacin ($C_{21}H_{24}FN_3O_4$).

Packaging and storage—Preserve in tight containers. Store between 2° and 25°.

USP Reference standards ⟨11⟩**—**
USP Moxifloxacin Hydrochloride RS
USP Moxifloxacin Related Compound A RS
1-Cyclopropyl-6,8-difluoro-1,4-dihydro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid.
$C_{20}H_{21}F_2N_3O_3$ 389.40

Identification—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.*