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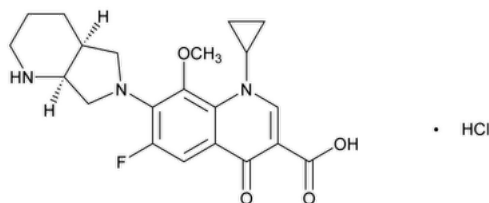
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# Moxifloxacin Hydrochloride


 $C_{21}H_{24}FN_3O_4 \cdot HCl$  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 CAS RN®: 186826-86-8; UNII: C53598599T.

## DEFINITION

Moxifloxacin Hydrochloride contains NLT 98.0% and NMT 102.0% of moxifloxacin hydrochloride ( $C_{21}H_{24}FN_3O_4 \cdot HCl$ ), calculated on the anhydrous basis.

## IDENTIFICATION

**Change to read:**

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chloride](#)

**Sample solution:** To a solution (1 in 160) add diluted nitric acid, and filter.

**Acceptance criteria:** Meets the requirements

## ASSAY

### PROCEDURE

**Buffer:** 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 filter of 0.45-μm pore size.

**Mobile phase:** Methanol and *Buffer* (28:72)

**Diluent:** Add 20 mg of [anhydrous sodium sulfite](#) to 1000 mL of *Buffer*, mix gently, and pass through a filter of 0.45-μm pore size.

**System suitability solution:** 0.1 mg/mL of [USP Moxifloxacin Hydrochloride RS](#) and 1 μg/mL of [USP Moxifloxacin Related Compound A RS](#), in *Diluent*

**Standard solution:** 0.1 mg/mL of [USP Moxifloxacin Hydrochloride RS](#) in *Diluent*

**Sample solution:** 0.1 mg/mL of Moxifloxacin Hydrochloride in *Diluent*

### Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** UV 293 nm

**Column:** 4.0-mm × 25-cm; 5-μm packing [L11](#)

**Column temperature:** 45°

**Flow rate:** 0.9 mL/min

**Injection volume:** 25 μL

### System suitability

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

[NOTE—The relative retention times for moxifloxacin and moxifloxacin related compound A are about 1.0 and 1.2, respectively.]

### Suitability requirements

**Resolution:** NLT 1.5 between moxifloxacin and moxifloxacin related compound A, *System suitability solution*

**Tailing factor:** NMT 2.0, *Standard solution*

**Relative standard deviation:** NMT 0.73%, *Standard solution*

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of moxifloxacin hydrochloride ( $C_{21}H_{24}FN_3O_4 \cdot HCl$ ) in the portion of Moxifloxacin Hydrochloride taken:

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

$r_U$  = peak response from the *Sample solution*

$r_S$  = peak response from the *Standard solution*

$C_S$  = concentration of [USP Moxifloxacin Hydrochloride RS](#) in the *Standard solution* (mg/mL)

$C_U$  = concentration of Moxifloxacin Hydrochloride in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the anhydrous basis

#### IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• [CHLORIDE AND SULFATE \(221\)](#), [Sulfate](#)

**Sample:** 0.6 g

**Acceptance criteria:** 0.04%; the *Sample* shows no more sulfate than corresponds to 0.25 mL of 0.020 N [sulfuric acid](#).

• **ORGANIC IMPURITIES**

Protect all solutions containing moxifloxacin from light.

**Mobile phase, Diluent, System suitability solution, and Sample solution:** Prepare as directed in the Assay.

**Standard solution:** 2 µg/mL of [USP Moxifloxacin Hydrochloride RS](#) in *Diluent*

**Sensitivity solution:** 0.05 µg/mL of [USP Moxifloxacin Hydrochloride RS](#) from the *Standard solution* in *Diluent*. Store the *Sensitivity solution* under refrigeration and protected from light.

**Chromatographic system:** Proceed as directed in the Assay with a run time of two times the retention time of moxifloxacin.

#### System suitability

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

#### Suitability requirements

**Resolution:** NLT 1.5 between moxifloxacin and moxifloxacin related compound A, *System suitability solution*

**Tailing factor:** NMT 2.0, *Standard solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*

#### Analysis

**Samples:** *Sample solution* and *Standard solution*

Calculate the percentage of each impurity in the portion of Moxifloxacin Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

$r_U$  = peak response of each impurity from the *Sample solution*

$r_S$  = peak response of moxifloxacin from the *Standard solution*

$C_S$  = concentration of [USP Moxifloxacin Hydrochloride RS](#) in the *Standard solution* (mg/mL)

$C_U$  = concentration of Moxifloxacin Hydrochloride in the *Sample solution* (mg/mL)

$F$  = relative response factor (see [Table 1](#))

**Acceptance criteria:** See [Table 1](#).

**Table 1**

| Name                                         | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) |
|----------------------------------------------|-------------------------|--------------------------|------------------------------|
| Moxifloxacin                                 | 1.0                     | —                        | —                            |
| Moxifloxacin related compound A <sup>a</sup> | 1.15                    | 1.0                      | 0.1                          |
| Moxifloxacin related compound B <sup>b</sup> | 1.32                    | 0.71                     | 0.1                          |



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