

Moxifloxacin Ophthalmic Solution

DEFINITION
Moxifloxacin Ophthalmic Solution is a sterile, self-preserved aqueous solution of Moxifloxacin Hydrochloride. It contains NLT 90.0% and NMT 110.0% of the labeled amount of moxifloxacin ($C_{21}H_{24}FN_3O_4$).

IDENTIFICATION

- A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- B.** The UV absorption spectra of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- PROCEDURE**
Solution A: Dissolve 0.5 g of tetrabutylammonium hydrogen sulfate and 1.0 g of monobasic potassium phosphate in 1000 mL of water. Add 2 mL of phosphoric acid, filter, and degas.
Solution B: Methanol
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Flow Rate (mL/min)	Solution A (%)	Solution B (%)
0	0.5	69	31
30	0.5	69	31
31	0.9	60	40
36	0.9	60	40
37	0.5	69	31
42	0.5	69	31

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

Standard stock solution: 6 mg/mL of [USP Moxifloxacin Hydrochloride RS](#) in water

Standard solution: 0.1 mg/mL of [USP Moxifloxacin Hydrochloride RS](#) in *Solution A* from the *Standard stock solution*

Sample solution: Nominally 0.1 mg/mL of moxifloxacin from Ophthalmic Solution in *Solution A*

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

Mode: LC

Detector: UV 293 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.0-mm × 25-cm; 5-µm packing L11

Column temperature: 45°

Flow rate: See [Table 1](#).

Injection volume: 25 µL

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

Suitability requirements**Resolution:** NLT 2.0 between the moxifloxacin and moxifloxacin related compound A peaks, *System suitability solution***Tailing factor:** NMT 2.0, *Standard solution***Relative standard deviation:** NMT 2.0%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of moxifloxacin ($C_{21}H_{24}FN_3O_4$) in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

 r_U = peak response of moxifloxacin 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 = nominal concentration of moxifloxacin in the *Sample solution* (mg/mL) M_{r1} = molecular weight of moxifloxacin, 401.43 M_{r2} = molecular weight of moxifloxacin hydrochloride, 437.89**Acceptance criteria:** 90.0%–110.0%**IMPURITIES****• ORGANIC IMPURITIES: EARLY-ELUTING RELATED COMPOUNDS (RELATIVE RETENTION LESS THAN 1.8)**Protect the *System suitability solution*, *Sample solution*, and *Standard solution* from light. Analyze the *Sample solution* immediately after preparation.**Solution A, Solution B, Mobile phase, System suitability solution, Standard stock solution, and Sample solution:** Prepare as directed in the Assay.**Blank solution:** Use *Solution A*.**Standard solution:** 2 µg/mL of [USP Moxifloxacin Hydrochloride RS](#) in *Solution A* from the *Standard stock solution***Sensitivity solution:** 0.05 µg/mL of [USP Moxifloxacin Hydrochloride RS](#) from the *Standard solution* in *Solution A*. Store the *Sensitivity solution* under refrigeration and protected from light.**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:** See [Table 1](#).**Injection volume:** 25 µL**System suitability****Samples:** *System suitability solution*, *Standard solution*, and *Sensitivity solution***Suitability requirements****Resolution:** NLT 2.0 between the moxifloxacin and moxifloxacin related compound A peaks, *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:** *Blank solution*, *Standard solution*, and *Sample solution*[NOTE—Determine the relative retention values (r) for components listed in [Table 2](#), using the time measured at the first baseline deflection of the *Standard solution* chromatogram as the void volume (t_M).]

Calculate the percentage of each impurity in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times (1/F) \times 100$$

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