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Levofloxacin Tablets

DEFINITION

Levofloxacin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of levofloxacin ($C_{18}H_{20}FN_3O_4$).

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.

Add the following:

▲ **B.** The UV absorption spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2021)

ASSAY

Change to read:

PROCEDURE

Diluent: [Acetonitrile](#) and [water](#) (20:80)

Mobile phase: Transfer 874 mg of [cupric sulfate](#), 918 mg of [L-isoleucine](#), and 5.94 g of [ammonium acetate](#) to a suitable container. Add 700 mL of [water](#), and mix until dissolved. Add 300 mL of [methanol](#).

Standard stock solution: 2 mg/mL of [USP Levofloxacin RS](#) in *Diluent*. ▲Sonicate, if necessary, to dissolve prior to final dilution.▲ (USP 1-May-2021)

Standard solution: 0.2 mg/mL of [USP Levofloxacin RS](#) in *Mobile phase* from the *Standard stock solution*

Sample stock solution: Nominally 5 mg/mL of levofloxacin prepared as follows. Transfer intact Tablets (NLT 5) to a volumetric flask, add 75% of the final volume of *Diluent*, and allow to stand for 15 min. Shake for 30 min, and dilute with *Diluent* to volume. Pass a portion of the solution through a suitable filter of 0.45-μm pore size, discarding the first 1–2 mL of the filtrate.

Sample solution: Nominally 0.2 mg/mL of levofloxacin in *Mobile phase* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 360 nm. ▲For *Identification B*, use a diode array detector in the range of 220–400 nm.▲ (USP 1-May-2021)

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 45°

Flow rate: 0.8 mL/min

Injection volume: 25 μL

Run time: 2 times the retention time of levofloxacin

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of levofloxacin ($C_{18}H_{20}FN_3O_4$) in the portion of Tablets taken:

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

r_U = peak response of levofloxacin from the *Sample solution*

r_S = peak response of levofloxacin from the *Standard solution*

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

C_U = nominal concentration of levofloxacin in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS• [DISSOLUTION \(711\)](#)**Test 1****Medium:** 0.1 N [hydrochloric acid](#); 900 mL**Apparatus 2:** 75 rpm**Time:** 30 min**Standard solution:** 0.56 mg/mL of [USP Levofloxacin RS](#) in *Medium***Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.**Instrumental conditions**(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV**Analytical wavelength:** 294 nm**Cell length:** 0.1 mm**Blank:** *Medium***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage (*Q*) of the labeled amount of levofloxacin ($C_{18}H_{20}FN_3O_4$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

 A_U = absorbance of the *Sample solution* A_S = absorbance of the *Standard solution* C_S = concentration of the *Standard solution* (mg/mL) V = volume of *Medium*, 900 mL D = dilution factor of the *Sample solution* L = label claim (mg/Tablet)**Tolerances:** NLT 80% (*Q*) of the labeled amount of levofloxacin ($C_{18}H_{20}FN_3O_4$) is dissolved.**Test 2****Medium:** 0.1 N [hydrochloric acid](#); 900 mL**Apparatus 1:** 100 rpm**Time:** 30 min**Standard solution:** $L/900$ mg/mL of [USP Levofloxacin RS](#) in *Medium*. Mix to obtain solutions with known concentrations as indicated in [Table 1](#), where L is the label claim in mg/Tablet.**Sample solution:** Pass a portion of the solution under test having a concentration similar to that of the *Standard solution* through a suitable filter of 0.45-µm pore size.**Table 1**

Tablet Label Claim (mg)	Final Concentration (mg/mL)
250	0.27
500	0.55
750	0.83

Instrumental conditions(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV**Analytical wavelength:** 293 nm**Cell length:** 0.1 mm**Blank:** *Medium***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage (*Q*) of the labeled amount of levofloxacin ($C_{18}H_{20}FN_3O_4$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$