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Linezolid Tablets

DEFINITION

Linezolid Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of linezolid ($C_{16}H_{20}FN_3O_4$).

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.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 0.23 g/L of [ammonium phosphate monobasic](#)

Mobile phase: [Methanol](#) and *Buffer* (55:45)

Diluent: [Methanol](#) and *Buffer* (45:55)

Standard solution: 0.06 mg/mL of [USP Linezolid RS](#) in *Diluent*. Sonicate to dissolve as necessary.

Sample stock solution: Nominally 1.2 mg/mL of linezolid from Tablets prepared as follows. Finely powder Tablets (NLT 10) and transfer a suitable portion of the powder to a suitable volumetric flask. Add *Buffer* in small portions to disperse the powder. Use *Buffer* equivalent to 55% of the final volume. Shake for about 10 min. Add [methanol](#), using 20% of the final volume, and sonicate for about 10 min. Allow this solution to stand for about 10 min. Dilute with [methanol](#) to volume.

Sample solution: Nominally 0.06 mg/mL of linezolid in *Diluent* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 251 nm

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

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.6 times the retention time of linezolid

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of linezolid ($C_{16}H_{20}FN_3O_4$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#)

Test 1

Medium: 0.05 M phosphate buffer pH 6.8; 900 mL, prepared as follows. Dissolve 6.8 g/L of [potassium phosphate monobasic](#) and 0.869 g/L of [sodium hydroxide](#) in [water](#).

Apparatus 2: 50 rpm

Time: 60 min

Buffer, Mobile phase, Diluent, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Standard stock solution: 0.4 mg/mL of [USP Linezolid RS](#) in *Diluent*. Sonicate, as needed, to dissolve.

Standard solution: 0.04 mg/mL of [USP Linezolid RS](#) in *Medium* from the *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size. Dilute the filtrate with *Medium* to obtain a final concentration similar to that of the *Standard solution*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of linezolid ($C_{16}H_{20}FN_3O_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times \Delta_D \text{ (ERR 1-Feb-2024)} \times 100$$

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

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

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Δ_D = dilution factor of the *Sample solution*, as needed Δ (ERR 1-Feb-2024)

Tolerances: NLT 80% (Q) of the labeled amount of linezolid ($C_{16}H_{20}FN_3O_4$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.05 M phosphate buffer pH 6.8; 900 mL, prepared as follows. Dissolve 6.8 g of [potassium phosphate monobasic](#) in 1 L of [water](#) and adjust if needed with [2.5 N sodium hydroxide TS](#) to a pH of 6.8.

Apparatus 2: 50 rpm

Time: 30 min

Mobile phase: [Acetonitrile](#) and [water](#) (25:75)

Standard solution: 0.0264 mg/mL of [USP Linezolid RS](#) in *Medium*. Sonicate, as needed, to dissolve.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size. Dilute the filtrate with *Medium* to obtain a final concentration similar to that of the *Standard solution*.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.6 times the retention time of linezolid

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of linezolid ($C_{16}H_{20}FN_3O_4$) dissolved:

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

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

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

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)