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Sildenafil Tablets

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DEFINITION

Sildenafil Tablets contain sildenafil citrate equivalent to NLT 90% and NMT 110% of the labeled amount of sildenafil ($C_{22}H_{30}N_6O_4S$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Solution A: [Ammonium hydroxide](#) and [water](#) (10:90)

Standard solution: 1.4 mg/mL of [USP Sildenafil Citrate RS](#) in *Solution A*

Sample solution: Grind 1 Tablet and add a sufficient amount of *Solution A* to obtain nominally 1 mg/mL of sildenafil. Sonicate for 2 min, shake well, and centrifuge. Use the supernatant.

Analysis: For each of the *Standard solution* and the *Sample solution*, prewash a 6-cc C18 solid phase extraction cartridge with 10 mL of [methanol](#) followed by 10 mL of *Solution A*, discarding both washings. Apply 5 mL each of the *Standard solution* and the *Sample solution* to separate prewashed cartridges and draw each solution through the cartridge. Wash each cartridge with 10 mL of [water](#) and allow the cartridge to dry under vacuum. Elute the sildenafil from each cartridge with 5 mL of [methanol](#), collecting the eluant in a suitable container. Add about 200 mg of [potassium bromide](#) to each container, mix well, and evaporate to dryness. To about 70 mg of each dried mixture, add about 140 mg of [potassium bromide](#) and mix.

Acceptance criteria: Meet the requirements

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

ASSAY

PROCEDURE

Buffer: Dilute 7 mL of [triethylamine](#) with [water](#) to 1 L. Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: *Buffer*, [methanol](#), and [acetonitrile](#) (58:25:17)

Diluent: [Acetonitrile](#) and [water](#) (90:10)

Standard solution: 0.028 mg/mL of [USP Sildenafil Citrate RS](#) in *Mobile phase*

Sample stock solution: Disperse 1 Tablet in at least 5 mL of *Diluent* with the aid of sonication. Once the Tablet is fully dispersed, dilute with *Mobile phase* to 250.0 mL while swirling. Centrifuge and use the supernatant.

Sample solution: Nominally 0.02 mg/mL of sildenafil prepared by diluting a suitable portion of the *Sample stock solution* with *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 290 nm

Column: 3.9-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.5 times the retention time of sildenafil

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.3

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sildenafil ($C_{22}H_{30}N_6O_4S$) in the portion of Tablets taken:

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

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

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

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

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

M_{r1} = molecular weight of sildenafil, 474.58

M_{r2} = molecular weight of sildenafil citrate, 666.70

Acceptance criteria: 90%–110%

PERFORMANCE TESTS

Change to read:

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

▲Test 1▲ (RB 1-Jan-2025)

Medium: 0.01 N [hydrochloric acid](#); 900 mL

Apparatus 1: 100 rpm

Time: 15 min

Standard solution: 0.03 mg/mL of [USP Sildenafil Citrate RS](#) in *Medium*

Sample solution: A filtered portion of the solution under test, suitably diluted with *Medium*, if necessary

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: Maximum at about 290 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sildenafil ($C_{22}H_{30}N_6O_4S$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

D = dilution factor for the *Sample solution*, if needed

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

M_{r1} = molecular weight of sildenafil, 474.58

M_{r2} = molecular weight of sildenafil citrate, 666.70

Tolerances: NLT 80% (Q) of the labeled amount of sildenafil ($C_{22}H_{30}N_6O_4S$) is dissolved.

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

Medium: 0.1 N [hydrochloric acid](#); 500 mL

Apparatus 1: 100 rpm

Time: 15 min

Standard solution: 0.03 mg/mL of [USP Sildenafil Citrate RS](#) in *Medium*. Sonicate to dissolve, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained. Dilute with *Medium* to a concentration similar to that of the *Standard solution*.

Instrumental conditions