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Add the following:

^Sildenafil Injection

DEFINITION

Sildenafil Injection is a sterile solution of Sildenafil Citrate in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of sildenafil ($C_{22}H_{30}N_6O_4S$). It also contains dextrose.

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

Solution A: 15.4 g/L of [ammonium acetate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Solution A* (50:50)

Standard solution: 0.11 mg/mL of [USP Sildenafil Citrate RS](#) in *Mobile phase*. Sonicate to dissolve if necessary.

Sample solution: Nominally 0.08 mg/mL of sildenafil prepared as follows. Transfer 5 mL of Injection to a 50-mL volumetric flask and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 245 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

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

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.6 times the retention time of sildenafil

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

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 Injection 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: 95.0%–105.0%

IMPURITIES

• ORGANIC IMPURITIES

Dilute phosphoric acid: 10% (v/v) [phosphoric acid](#) in [water](#)

Buffer: 3.5 g/L of [potassium phosphate, dibasic](#) in [water](#). Adjust with *Dilute phosphoric acid* to a pH of 7.0.

Solution A: [Acetonitrile](#) and *Buffer* (14:86)

Solution B: [Acetonitrile](#) and *Buffer* (74:26)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	78	22
5	78	22
20	50	50
30	40	60
35	78	22
40	78	22

Diluent: [Methanol](#) and [water](#) (50:50)

Standard stock solution: 0.46 mg/mL of [USP Sildenafil Citrate RS](#) in [methanol](#). Sonicate to dissolve if necessary.

Standard solution: 1.15 µg/mL of [USP Sildenafil Citrate RS](#) from the *Standard stock solution* in *Diluent*

Sensitivity solution: 0.575 µg/mL of [USP Sildenafil Citrate RS](#) from the *Standard solution* in *Diluent*

Sample solution: Nominally 0.4 mg/mL of sildenafil prepared as follows. Transfer 5 mL of Injection to a 10-mL volumetric flask and dilute with [methanol](#) to volume.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

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

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sildenafil N-oxide and any unspecified degradation product in the portion of Injection 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 degradation product 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)