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Spironolactone Tablets

DEFINITION

Spironolactone Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of spironolactone ($C_{24}H_{32}O_4S$).

IDENTIFICATION

Change to read:

- **A.** ▲The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2021)

Add the following:

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

ASSAY

Change to read:

• PROCEDURE

Mobile phase: [Methanol](#) and [water](#) (60:40)

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

Standard solution: 0.5 mg/mL of [USP Spironolactone RS](#) in *Diluent*

Sample stock solution: Nominally 1 mg/mL of spironolactone in *Diluent* prepared as follows. Weigh NLT 10 Tablets, and transfer to a suitable volumetric flask. ▲▲ (USP 1-Aug-2021) Add a sufficient quantity of *Diluent*, shake for about 30 min, and sonicate for 30 min or until the Tablets are disintegrated. Cool the solution to room temperature, dilute with *Diluent* to volume, and centrifuge a suitable portion of the mixture.

Sample solution: Nominally 0.5 mg/mL of spironolactone in *Diluent* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm. ▲For *Identification B*, use a diode array detector in the range of 210–400 nm.▲ (USP 1-Aug-2021)

Column: 4.6-mm × 15-cm; ▲5-μm▲ (USP 1-Aug-2021) packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 μL

▲**Run time:** NLT 2 times the retention time of spironolactone▲ (USP 1-Aug-2021)

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of spironolactone ($C_{24}H_{32}O_4S$) in the portion of Tablets taken:

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

r_U = peak response ▲of spironolactone▲ (USP 1-Aug-2021) from the *Sample solution*

r_s = peak response $\blacktriangle$ of spironolactone $\blacktriangle$ (USP 1-Aug-2021) from the *Standard solution*

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

C_u = nominal concentration of spironolactone in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid containing 0.1% of [sodium dodecyl sulfate](#); 1000 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: A known concentration of [USP Spironolactone RS](#) in *Medium*. [NOTE—A volume of alcohol not exceeding 1% of the final volume of the solution may be used to prepare the *Standard solution*.]

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, as necessary in comparison with the *Standard solution*.

Instrumental conditions

$\blacktriangle$ (See [Ultraviolet-Visible Spectroscopy \(857\)](#).) $\blacktriangle$ (USP 1-Aug-2021)

Mode: UV

Analytical wavelength: 242 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the $\blacktriangle$ percentage of the labeled $\blacktriangle$ (USP 1-Aug-2021) amount of spironolactone ($C_{24}H_{32}O_4S$) dissolved:

$$\blacktriangle \text{Result} = (A_u/A_s) \times C_s \times D \times V \times (1/L) \times 100$$

A_u = absorbance of the *Sample solution*

A_s = absorbance of the *Standard solution*

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

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 1000 mL

L = label claim of spironolactone (mg/Tablet)

$\blacktriangle$ (USP 1-Aug-2021)

Tolerances: NLT 75% (Q) of the labeled amount of spironolactone ($C_{24}H_{32}O_4S$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

Add the following:

$\blacktriangle$ IMPURITIES

• ORGANIC IMPURITIES

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

Mobile phase: [Acetonitrile](#), [tetrahydrofuran](#), [methanol](#), and [water](#) (15:20:425:540)

Standard stock solution A: 100 μ g/mL of [USP Spironolactone RS](#) prepared as follows. Dissolve a suitable amount of [USP Spironolactone RS](#) in a suitable volumetric flask in about 10% of the total volume with [tetrahydrofuran](#). Dilute with *Diluent* to volume.

Standard stock solution B: 100 μ g/mL of [USP Spironolactone Related Compound A RS](#) prepared as follows. Dissolve a suitable amount of [USP Spironolactone Related Compound A RS](#) in a suitable volumetric flask in about 10% of the total volume with [tetrahydrofuran](#). Dilute with *Diluent* to volume.

Sensitivity solution: 2 μ g/mL of [USP Spironolactone RS](#) in *Diluent*, from *Standard stock solution A*

Standard solution: 4 μ g/mL each of [USP Spironolactone RS](#) and [USP Spironolactone Related Compound A RS](#) in *Diluent*, from *Standard stock solution A* and *Standard stock solution B*