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Triamterene and Hydrochlorothiazide Tablets

DEFINITION

Triamterene and Hydrochlorothiazide Tablets contain NLT 90.0% and NMT 110.0% of the labeled amounts of triamterene ($C_{12}H_{11}N_7$) and hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$).

[NOTE—The Capsules and Tablets dosage forms should not be considered bioequivalent. If patients are to be transferred from one dosage form to the other, retitration and appropriate changes in dosage may be necessary.]

IDENTIFICATION

Change to read:

• **A.** The retention [▲]times of the major peaks [▲](USP 1-Dec-2019) of the *Sample solution* [▲]correspond to those of [▲](USP 1-Dec-2019) the *Standard solution*, as obtained in the Assay.

Change to read:

• **B.** [▲]The UV spectra of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay. [▲](USP 1-Dec-2019)

ASSAY

Change to read:

• PROCEDURE

Buffer: [▲]Dissolve 0.82 g of [sodium acetate anhydrous](#) in 1000 mL of [water](#), and adjust with [glacial acetic acid](#) to a pH of 4.5. [▲](USP 1-Dec-2019)

Mobile phase: [Acetonitrile](#) and *Buffer* [▲](35:65) [▲](USP 1-Dec-2019)

Diluent: [Acetonitrile](#), [glacial acetic acid](#), and [water](#) [▲](350:35:650)

System suitability stock solution: 1.5 µg/mL of [USP Benzothiadiazine Related Compound A RS](#) in *Diluent*. Sonicate the solution to aid the dissolution.

Standard stock solution: 0.75 mg/mL of [USP Triamterene RS](#) and 0.50 mg/mL of [USP Hydrochlorothiazide RS](#) in *Diluent*. Sonicate the solution to aid the dissolution.

System suitability solution: 22.5 µg/mL of [USP Triamterene RS](#), 15 µg/mL of [USP Hydrochlorothiazide RS](#), and 0.075 µg/mL of [USP Benzothiadiazine Related Compound A RS](#) from the *Standard stock solution* and *System suitability stock solution*, diluted with *Mobile phase*

Standard solution: 0.023 mg/mL of [USP Triamterene RS](#) and 0.015 mg/mL of [USP Hydrochlorothiazide RS](#) in *Mobile phase* from *Standard stock solution*

Sample stock solution: Nominally 0.5 mg/mL of hydrochlorothiazide in *Diluent* prepared as follows. Transfer a suitable number of Tablets (NLT 10) to a suitable volumetric flask. Add *Diluent* to 80% of the flask volume and sonicate for 30 min. Dilute with *Diluent* to volume. Centrifuge and use the supernatant. [▲](USP 1-Dec-2019)

Sample solution: [▲]Nominally 0.015 mg/mL of hydrochlorothiazide from the *Sample stock solution*, diluted with *Mobile phase* [▲](USP 1-Dec-2019)

Chromatographic system

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

Mode: LC

Detector: [▲]UV 272 nm. For *Identification B*, use a diode array detector in the range of 190–400 nm. [▲](USP 1-Dec-2019)

Column: [▲]4.6-mm × 25-cm; 5-µm packing [L1](#) [▲](USP 1-Dec-2019)

Flow rate: [▲]1 mL/min [▲](USP 1-Dec-2019)

Injection volume: [▲]20 µL

Run time: NLT 2 times the retention time of hydrochlorothiazide [▲](USP 1-Dec-2019)

System suitability

▲**Samples:** *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for benzothiadiazine related compound A and hydrochlorothiazide are 0.93 and 1.0, respectively.]▲ (USP 1-Dec-2019)

Suitability requirements

Resolution:▲ NLT 1.5 between hydrochlorothiazide and benzothiadiazine related compound A, *System suitability solution*▲ (USP 1-Dec-2019)

Relative standard deviation: NMT 2.0%, ▲*Standard solution*▲ (USP 1-Dec-2019)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amounts of triamterene ($C_{12}H_{11}N_7$) and hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$) in the portion of Tablets taken:

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

r_U = peak response of triamterene or hydrochlorothiazide from the *Sample solution*

r_S = peak response of triamterene or hydrochlorothiazide from the *Standard solution*

C_S = concentration of ▲[USP Triamterene RS](#) or [USP Hydrochlorothiazide RS](#)▲ (USP 1-Dec-2019) in the *Standard solution* (mg/mL)

C_U = nominal concentration of triamterene or hydrochlorothiazide in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

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

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 75 rpm

Time: 30 min

▲**Buffer:** Transfer 6.9 g of [monobasic sodium phosphate](#) and 1.43 g of propylamine hydrochloride to a 1-L volumetric flask. Dissolve in 900 mL of [water](#), adjust with 1 N [sodium hydroxide](#) to a pH of 5.5, and dilute with [water](#) to volume.

Mobile phase: [Acetonitrile](#) and *Buffer* (20:80)▲ (USP 1-Dec-2019)

Standard solution: [USP Triamterene RS](#) and [USP Hydrochlorothiazide RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

▲**Chromatographic system**

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

Mode: LC

Detector: UV 280 nm

Column: 4.0-mm × 25-cm; packing L1

Flow rate: 1.2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for hydrochlorothiazide and triamterene are 0.65 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between hydrochlorothiazide and triamterene

Relative standard deviation: NMT 2.0%▲ (USP 1-Dec-2019)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amounts of triamterene ($C_{12}H_{11}N_7$) and hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$) dissolved:

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

r_U = peak response of triamterene or hydrochlorothiazide from the *Sample solution*

r_S = peak response of triamterene or hydrochlorothiazide from the *Standard solution*