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Moexipril Hydrochloride and Hydrochlorothiazide Tablets

DEFINITION

Moexipril Hydrochloride and Hydrochlorothiazide Tablets contain NLT 90.0% and NMT 110.0% each of the labeled amounts of moexipril hydrochloride ($C_{27}H_{34}N_2O_7 \cdot HCl$) and hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$).

IDENTIFICATION

• **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

Add the following:

▲• **B.** The UV spectra of the major peaks of the *Diluted sample solution* correspond to those of the *Diluted standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2020)

ASSAY

Change to read:

• **PROCEDURE**

Buffer: 0.01 M [potassium dihydrogen phosphate](#)

Mobile phase: [Acetonitrile](#) and *Buffer* (35:65)

Diluent: [Acetonitrile](#) and [water](#) (30:70)

Standard solution: Prepare solutions of [USP Moexipril Hydrochloride RS](#) and [USP Hydrochlorothiazide RS](#) in *Diluent*, of concentrations stated in [Table 1](#). Initially add *Diluent* to 70% of the total volume, sonicate to dissolve, and then dilute with *Diluent* to volume.

Table 1

Tablet Strength Moexipril Hydrochloride/ Hydrochlorothiazide (mg/mg)	Concentration of Moexipril Hydrochloride (mg/mL)	Concentration of Hydrochlorothiazide (mg/mL)
7.5/12.5	0.06	0.1
15/12.5	0.06	0.05
15/25	0.06	0.1

▲**Diluted standard solution:** *Standard solution* and *Diluent* (50:50)▲ (USP 1-Aug-2020)

Sample solution: The nominal concentrations of moexipril and hydrochlorothiazide in mg/mL given in [Table 1](#) prepared as follows from powdered Tablets (NLT 20). Initially add *Diluent* to about 60% of the total volume, sonicate for 45 min with intermittent shaking, and then dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-µm pore size.

▲**Diluted sample solution:** *Sample solution* and *Diluent* (50:50)▲ (USP 1-Aug-2020)

Chromatographic system

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

Mode: LC

Detector: UV 210 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Aug-2020)

Column: 4.6-mm × 25-cm; 5-µm packing [L7](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: ▲NLT▲ (USP 1-Aug-2020) 2.2 times the retention time of the moexipril peak

System suitability

Sample: *Standard solution*

▲[NOTE—The relative retention times for hydrochlorothiazide and moexipril are 0.43 and 1.00, respectively.]▲ (USP 1-AUG-2020)

Suitability requirements

▲▲ (USP 1-Aug-2020)

Tailing factor: NMT 2.0 for both the moexipril and hydrochlorothiazide peaks

Relative standard deviation: NMT 2.0% for both the moexipril and hydrochlorothiazide peaks

Analysis

Samples: *Standard solution*, ▲*Diluted standard solution*, ▲ (USP 1-Aug-2020) *Sample solution*, and ▲*Diluted sample solution*

[NOTE—The *Diluted standard solution* and *Diluted sample solution* are used for *Identification B*.]▲ (USP 1-Aug-2020)

Calculate the percentage of the labeled amounts of moexipril hydrochloride ($C_{27}H_{34}N_2O_7 \cdot HCl$) 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 moexipril or hydrochlorothiazide from the *Sample solution*

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

C_S = concentration of [USP Moexipril Hydrochloride RS](#) or [USP Hydrochlorothiazide RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0% each of the labeled amounts of moexipril hydrochloride and hydrochlorothiazide

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

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

Apparatus 2: 50 rpm

Time: 15 min

Buffer, Mobile phase, ▲▲ (USP 1-Aug-2020) **Chromatographic system,** and **System suitability:** Proceed as directed in the Assay.

Standard solution: Prepare solutions of [USP Moexipril Hydrochloride RS](#) and [USP Hydrochlorothiazide RS](#) in *Medium* of concentrations stated in [Table 2](#).

Table 2

Tablet Strength Moexipril Hydrochloride/ Hydrochlorothiazide (mg/mg)	Concentration of USP Moexipril Hydrochloride RS (µg/mL)	Concentration of USP Hydrochlorothiazide RS (µg/mL)
7.5/12.5	8	14
15/12.5	16	14
15/25	16	28

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size, discarding the first 2–3 mL.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amounts of moexipril hydrochloride ($C_{27}H_{34}N_2O_7 \cdot HCl$) and hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$) dissolved:

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

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

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

C_S = concentration of [USP Moexipril Hydrochloride RS](#) or [USP Hydrochlorothiazide RS](#) in the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim for moexipril hydrochloride or hydrochlorothiazide (mg/Tablet)