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Moexipril Hydrochloride Tablets

DEFINITION

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

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Ultraviolet-Visible Spectroscopy*: **197U** ▲ (CN 1-MAY-2020)
- **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: 0.01 M potassium dihydrogen phosphate

Diluent: Acetonitrile and water (30:70)

Mobile phase: Acetonitrile and *Buffer* (350:650)

Standard solution: 0.075 mg/mL of [USP Moexipril Hydrochloride RS](#) in *Diluent*. Initially fill with *Diluent* to about 70% of the total volume, and sonicate. Further dilute with *Diluent* to volume.

Sample solution: Nominally 0.075 mg/mL of moexipril hydrochloride in *Diluent*, prepared from a sufficient number of crushed Tablets as follows. Add *Diluent* to about 75% of the total volume, and sonicate for 30 min with intermittent shaking. Dilute with *Diluent* to volume, and pass through a suitable filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-μm packing L7

Column temperature: 45°

Flow rate: 1.5 mL/min

Injection volume: 20 μL

Run time: 4 times the retention time of the moexipril peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of moexipril hydrochloride ($C_{27}H_{34}N_2O_7 \cdot HCl$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

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

Test 1

Buffer, Diluent, Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 15 min

Standard stock solution: 0.16 mg/mL of [USP Moexipril Hydrochloride RS](#) in *Diluent*. [NOTE—Sonication may be necessary for complete dissolution.]

Standard solution: 0.016 mg/mL of [USP Moexipril Hydrochloride RS](#) in *Medium* from the *Standard stock solution* for 15-mg Tablet strength and 0.008 mg/mL of [USP Moexipril Hydrochloride RS](#) in *Medium* from the *Standard stock solution* for 7.5-mg Tablet strength

Sample solution: Pass 10 mL 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 amount of moexipril hydrochloride ($C_{27}H_{34}N_2O_7 \cdot HCl$) dissolved:

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

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

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

C_S = concentration of [USP Moexipril Hydrochloride RS](#) in the *Standard solution*

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of moexipril hydrochloride ($C_{27}H_{34}N_2O_7 \cdot HCl$) is dissolved.

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

Buffer, Diluent, Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Medium, Apparatus 2, Standard stock solution, Standard solution, Sample solution, and Analysis: Proceed as directed in *Test 1*.

Time: 30 min

Tolerances: NLT 80% (Q) of the labeled amount of moexipril hydrochloride ($C_{27}H_{34}N_2O_7 \cdot HCl$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements for *Content Uniformity*

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 0.025% trifluoroacetic acid in water

Solution B: Acetonitrile and tetrahydrofuran (90:10)

Diluent: Acetonitrile and water (30:70)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
50	30	70
60	95	5
70	95	5

Impurity stock solution: 0.12 mg/mL of [USP Moexipril Related Compound G RS](#) in *Diluent*. [NOTE—Sonication may be necessary for complete dissolution.]

System suitability solution: 1.2 mg/mL of [USP Moexipril Hydrochloride RS](#) and 2.4 µg/mL of [USP Moexipril Related Compound G RS](#) from the *Impurity stock solution* in *Diluent*. [NOTE—Sonication may be necessary for complete dissolution.]

Standard stock solution: 1.2 mg/mL of [USP Moexipril Hydrochloride RS](#) in *Diluent*. Initially add *Diluent* to about 60% of the volume of the flask, and sonicate with intermittent shaking for complete dissolution.

Standard solution: 6 µg/mL each of [USP Moexipril Related Compound A RS](#) and [USP Moexipril Related Compound B RS](#), and 1.2 µg/mL of [USP Moexipril Hydrochloride RS](#) in *Diluent* from the *Standard stock solution*. [NOTE—Sonication may be necessary for complete dissolution.]

Sample solution: Nominally 1.2 mg/mL of moexipril hydrochloride in *Diluent*, prepared from a sufficient number of crushed Tablets. Initially add *Diluent* to about 60% of the volume of the flask, and sonicate for 20 min with intermittent shaking in ice cold water. Dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-µm pore size.

Chromatographic system