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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

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.5 between moexipril and moexipril related compound G, *System suitability solution*

Tailing factor: NMT 2.0 for the moexipril peak, *System suitability solution*

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

Analysis

Samples: *System suitability solution*, *Standard solution*, and *Sample solution*

Calculate the percentage of moexipril related compound A and moexipril related compound B 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 related compound A and moexipril related compound B from the *Sample solution*

r_S = peak response of moexipril related compound A and moexipril related compound B from the *Standard solution*

C_S = concentration of USP Moexipril Related Compound A RS and USP Moexipril Related Compound B RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any other individual unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of any other individual unspecified degradation product 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* (mg/mL)

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

Acceptance criteria: See *Table 2*. Disregard peaks less than 0.1%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Moexipril related compound E[a]	0.31	—
Moexipril related compound F[a]	0.77	—
Moexipril related compound A[b]	0.85	2.0
Moexipril related compound G[a]	0.94	—
Moexipril	1.00	—
Moexipril related compound D[a]	1.17	—

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Moexipril related compound C[a]	1.27	—
Moexipril related compound B[c]	1.43	1.5
Any unspecified degradation product	—	0.2
Total impurities[d]	—	2.0

[a] Process-related impurities controlled in the drug substance.

[b] (3*S*)-2-{(2*S*)-*N*-[(1*S*)-1-Carboxy-3-phenylpropyl]alanyl}-1,2,3,4-tetrahydro-6,7-dimethoxy-3-isoquinolinecarboxylic acid.

[c] (*S*)-Ethyl 2-{(3*S*,11a*S*)-8,9-dimethoxy-3-methyl-1,4-dioxo-3,4-dihydro-1*H*-pyrazino[1,2-*b*]isoquinolin-2(6*H*,11*H*,11a*H*)-yl}-4-phenylbutanoate.

[d] Total impurities do not include moexipril related compound A.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Store at controlled room temperature in tight, well-closed containers, and protect from moisture.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the test used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩

USP Moexipril Hydrochloride RS

USP Moexipril Related Compound A RS

(3*S*)-2-{(2*S*)-*N*-[(1*S*)-1-Carboxy-3-phenylpropyl]alanyl}-1,2,3,4-tetrahydro-6,7-dimethoxy-3-isoquinolinecarboxylic acid.

$C_{25}H_{30}N_2O_7$ 470.51

USP Moexipril Related Compound B RS

(*S*)-Ethyl 2-{(3*S*,11a*S*)-8,9-dimethoxy-3-methyl-1,4-dioxo-3,4-dihydro-1*H*-pyrazino[1,2-*b*]isoquinolin-2(6*H*,11*H*,11a*H*)-yl}-4-phenylbutanoate.

$C_{27}H_{32}N_2O_6$ 480.55

USP Moexipril Related Compound G RS

(*S*)-6,7-Dimethoxy-2-{(*S*)-2-[(*S*)-1-methoxy-1-oxo-4-phenylbutan-2-ylamino]propanoyl}-1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid.

$C_{26}H_{32}N_2O_7$ 484.54

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MOEXIPRIL HYDROCHLORIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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