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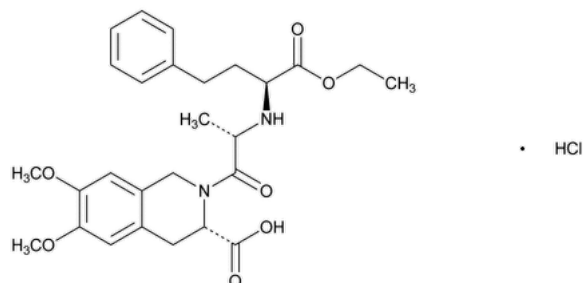
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# Moexipril Hydrochloride


 $C_{27}H_{34}N_2O_7 \cdot HCl$  535.03

3-Isoquinolinecarboxylic acid, 2-[2-[[1-(ethoxycarbonyl)-3-phenylpropyl]amino]-1-oxopropyl]-1,2,3,4-tetrahydro-6,7-dimethoxy-, monohydrochloride, [3S-[2[R\*(R\*),3R\*]]]-; (3S)-2-[(2S)-N-[(1S)-1-Carboxy-3-phenylpropyl]alanyl]-1,2,3,4-tetrahydro-6,7-dimethoxy-3-isoquinolinecarboxylic acid, 2-ethyl ester, monohydrochloride CAS RN®: 82586-52-5; UNII: Q1UMG3UH45.

## DEFINITION

Moexipril Hydrochloride contains NLT 98.0% and NMT 102.0% of moexipril hydrochloride ( $C_{27}H_{34}N_2O_7 \cdot HCl$ ), calculated on the anhydrous basis.

## IDENTIFICATION

**Change to read:**

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** The relative retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\), Chloride](#): Meets the requirements

## ASSAY

### PROCEDURE

**Buffer:** 1.32 g/L of dibasic ammonium phosphate. Adjust with diluted phosphoric acid to a pH of 7.5.

**Solution A:** Acetonitrile and tetrahydrofuran (95:5)

**Mobile phase:** *Solution A* and *Buffer* (30:70)

**Standard solution:** 0.1 mg/mL of [USP Moexipril Hydrochloride RS](#) in *Mobile phase*. [NOTE—Sonication may be necessary for complete dissolution.]

**Sample solution:** 0.1 mg/mL of Moexipril Hydrochloride in *Mobile phase*. [NOTE—Sonication may be necessary for complete dissolution.]

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 215 nm

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

**Column temperature:** 35°

**Flow rate:** 1 mL/min

**Injection volume:** 10 μL

**Run time:** NLT 3.2 times the retention time of moexipril

### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Relative standard deviation:** NMT 2.0%

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of moexipril hydrochloride ( $C_{27}H_{34}N_2O_7 \cdot HCl$ ) in the portion of Moexipril Hydrochloride 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)

$C_U$  = concentration of Moexipril Hydrochloride in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the anhydrous basis

#### IMPURITIES

• **RESIDUE ON IGNITION** (281): NMT 0.20%

• **ORGANIC IMPURITIES**

[NOTE—Use freshly prepared samples for analysis.]

**Solution A** and **Chromatographic system:** Proceed as directed in the Assay.

**Solution B:** Proceed as directed for the *Buffer* in the Assay.

**Diluent:** *Solution A* and *Solution B* (20:80)

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

**Table 1**

| Time (min) | Solution A (%) | Solution B (%) |
|------------|----------------|----------------|
| 0          | 20             | 80             |
| 5          | 20             | 80             |
| 35         | 55             | 45             |
| 65         | 55             | 45             |
| 70         | 20             | 80             |
| 80         | 20             | 80             |

**Standard solution 1:** 4 µg/mL of [USP Moexipril Hydrochloride RS](#) in *Diluent*. [NOTE—Sonication may be necessary for complete dissolution.]

**Standard solution 2:** 2 mg/mL of [USP Moexipril Hydrochloride RS](#) and 3 µg/mL each of [USP Moexipril Related Compound A RS](#), [USP Moexipril Related Compound B RS](#), [USP Moexipril Related Compound C RS](#), [USP Moexipril Related Compound D RS](#), [USP Moexipril Related Compound E RS](#), [USP Moexipril Related Compound F RS](#), and [USP Moexipril Related Compound G RS](#) in *Diluent*. [NOTE—Sonication may be necessary for complete dissolution.]

**Sample solution:** 2 mg/mL of Moexipril Hydrochloride in *Diluent*. [NOTE—Sonication may be necessary for complete dissolution.]

#### System suitability

**Samples:** *Standard solution 1* and *Standard solution 2*

#### Suitability requirements

**Resolution:** NLT 3.5 between moexipril related compound A and moexipril related compound E; NLT 2.5 between moexipril and moexipril related compound G, *Standard solution 2*

**Relative standard deviation:** NMT 5.0% for moexipril, *Standard solution 1*

#### Analysis

**Samples:** *Standard solution 1*, *Standard solution 2*, and *Sample solution*

Calculate the percentage of each specified impurity in the portion of Moexipril Hydrochloride taken:

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

$r_U$  = peak response of each specified impurity from the *Sample solution*

$r_S$  = peak response of the corresponding Reference Standard from *Standard solution 2*

$C_S$  = concentration of each specified impurity in *Standard solution 2* (mg/mL)

$C_U$  = concentration of Moexipril Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of any other individual unspecified impurity in the portion of Moexipril Hydrochloride taken:

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