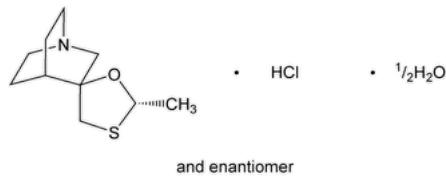


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Add the following:

▲Cevimeline Hydrochloride



$C_{10}H_{17}NOS \cdot HCl \cdot \frac{1}{2} H_2O$ 244.78
 $C_{10}H_{17}NOS$ 199.31
Spiro[1-azabicyclo[2.2.2]octane-3,5'-[1,3]oxathiolane], 2'-methyl-,hydrochloride, hydrate (2:1), *cis*-.
(±)-*cis*-2-Methylspiro[1,3-oxathiolane-5,3'-quinuclidine] hydrochloride, hemihydrate.
(2*RS*,2'*RS*)-2'-Methyl-4-azaspiro[bicyclo[2.2.2]octane-2,5'-[1,3]oxathiolane} hydrochloride hemihydrate CAS RN®: 153504-70-2; UNII: P81Q6V85NP.
Free base CAS RN®: 107233-08-9; UNII: K9V0CDQ56E.

DEFINITION

Cevimeline Hydrochloride contains NLT 98.0% and NMT 102.0% of cevimeline hydrochloride ($C_{10}H_{17}NOS \cdot HCl$) calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197A or 197K
- **B.** The 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), *Chemical Identification Tests, Chloride*: Meets the requirements

ASSAY

• PROCEDURE

Solution A: To each liter of [water](#), add 1.0 mL of [phosphoric acid](#) and 1.0 g of [sodium 1-hexanesulfonate monohydrate](#).
Solution B: To each liter of [acetonitrile](#), add 1.0 mL of [phosphoric acid](#).
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
3.4	89	11
10.7	10	90
12.7	10	90
13.0	95	5
14.0	95	5

Diluent: [Acetonitrile](#) and [water](#) (50:50)
System suitability solution: 0.022 mg/mL of [USP Cevimeline trans-Isomer RS](#) and 7.4 mg/mL of [USP Cevimeline Hydrochloride RS](#) in Diluent
Standard solution: 0.2 mg/mL of [USP Cevimeline Hydrochloride RS](#) in Diluent. Sonication may be used to promote dissolution.
Sample solution: 0.2 mg/mL of Cevimeline Hydrochloride in Diluent. Sonication may be used to promote dissolution

Chromatographic system

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

Mode: LC

Detector: UV 200 nm

Column: 2.1-mm × 5-cm; 1.7-μm packing [L1](#)

Column temperature: 60°

Flow rate: 0.7 mL/min

Injection volume: 1 μL

System suitability

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

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between cevimeline and cevimeline *trans*-isomer, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cevimeline hydrochloride ($C_{10}H_{17}NOS \cdot HCl$) in the portion of Cevimeline Hydrochloride taken:

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

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

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

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

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

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

Solution A, Solution B, Mobile phase, Diluent, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Standard stock solution: 0.44 mg/mL of [USP Cevimeline Hydrochloride RS](#) in *Diluent*. Sonication may be used to promote dissolution.

Standard solution: 0.022 mg/mL of [USP Cevimeline Hydrochloride RS](#) from *Standard stock solution* in *Diluent*. Sonication may be used to promote dissolution.

Sensitivity solution: 0.011 mg/mL of [USP Cevimeline Hydrochloride RS](#) from *Standard solution* in *Diluent*

Sample solution A: 7.4 mg/mL of Cevimeline Hydrochloride in *Diluent*. Sonication may be used to promote dissolution.

Sample solution B: 22.1 mg/mL of Cevimeline Hydrochloride in *Diluent*. Sonication may be used to promote dissolution.

System suitability

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

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between cevimeline and cevimeline *trans*-isomer, *System suitability solution*

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

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution*, *Sample solution A*, and *Sample solution B*

Calculate the percentage of cevimeline *trans*-isomer in the portion of Cevimeline Hydrochloride taken:

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

r_U = peak response of cevimeline *trans*-isomer from *Sample solution A*

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

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

C_U = concentration of Cevimeline Hydrochloride in *Sample solution A* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Cevimeline Hydrochloride taken:

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