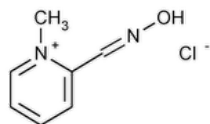


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-05D781B1-3C8F-4D28-A48D-C68EE63C168E_5_en-US
DOI: https://doi.org/10.31003/USPNF_M68220_05_01
DOI Ref: do3p0

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Pralidoxime Chloride



$C_7H_9ClN_2O$ 172.61

Pyridinium, 2-[(hydroxyimino)methyl]-1-methyl-, chloride (*E*)-;

(*E*)-2-Formyl-1-methylpyridinium chloride oxime CAS RN[®]: 14018-50-9.

Unspecified isomer CAS RN[®]: 51-15-0; UNII: 38X7XS076H.

DEFINITION

Pralidoxime Chloride contains NLT 97.0% and NMT 102.0% of pralidoxime chloride ($C_7H_9ClN_2O$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** **▲ SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A, 197K, or 197M ▲ (CN 1-May-2020)
- **B.** **IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Chloride:** A solution (1 in 10) meets the requirements.
- **C.** 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

Solution A: Prepare a solution containing 8 mM sodium octanesulfonate and 2 mM tetraethylammonium chloride as follows. Transfer 1.87 g of [sodium octanesulfonate monohydrate](#) and 330 mg of [tetraethylammonium chloride](#) to a 1-L volumetric flask, add [water](#) to dissolve the mixture, and dilute with water to volume. Adjust with [0.01 N hydrochloric acid](#) to a pH of 4.3.

Mobile phase: [Acetonitrile](#) and *Solution A* (17:83)

Diluent: [Acetonitrile](#) and [water](#) (17:83)

Standard stock solution: 1.25 mg/mL of [USP Pralidoxime Chloride RS](#) in [water](#). Use sonication to dissolve, if necessary.

Standard solution: 0.125 mg/mL of [USP Pralidoxime Chloride RS](#) in *Diluent* from the *Standard stock solution*

Sample stock solution: 1.25 mg/mL of Pralidoxime Chloride in [water](#). Use sonication to dissolve if necessary.

Sample solution: 0.125 mg/mL of Pralidoxime Chloride in *Diluent* from the *Sample stock solution*. [NOTE—This solution is stable for up to 6 h when stored at room temperature protected from light.]

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 15-cm; 3- or 3.5-μm packing L1

Flow rate: 0.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

[NOTE—[USP Pralidoxime Chloride RS](#) contains pralidoxime *anti*-isomer as a minor component. The relative retention times for pralidoxime *anti*-isomer and pralidoxime are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the pralidoxime *anti*-isomer and pralidoxime peaks

Tailing factor: NMT 1.5 for the pralidoxime chloride peak

Relative standard deviation: NMT 0.73% for the pralidoxime chloride peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pralidoxime chloride ($C_7H_9ClN_2O$) in the portion of Pralidoxime Chloride taken:

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

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

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

C_S = concentration of [USP Pralidoxime Chloride RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Pralidoxime Chloride in the *Sample solution* (µg/mL)

Acceptance criteria: 97.0%–102.0% on the dried basis

OTHER COMPONENTS

• CONTENT OF CHLORIDE

Sample solution: Dissolve 300 mg of Pralidoxime Chloride in 150 mL of [water](#).

Analysis: Add 20 mL of [glacial acetic acid](#) and 10 drops of (*p*-[tert-octylphenoxy](#))[nonaethoxyethanol](#) to the *Sample solution*, and titrate with [0.1 N silver nitrate VS](#), determining the endpoint potentiometrically. Perform a blank determination, and make any necessary corrections. Each milliliter of 0.1 N silver nitrate is equivalent to 3.545 mg of chloride.

Acceptance criteria: 20.2%–20.8% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

• ORGANIC IMPURITIES

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

Standard stock solution: Use the *Standard solution* prepared as directed in the Assay.

Standard solution: 0.125 µg/mL of [USP Pralidoxime Chloride RS](#) in *Diluent* from the *Standard stock solution*

Sensitivity solution: 0.0625 µg/mL of [USP Pralidoxime Chloride RS](#) in *Diluent* from the *Standard solution*

System suitability

Samples: *Standard stock solution*, *Standard solution*, and *Sensitivity solution*

Suitability requirements

Resolution: NLT 2.0 between the pralidoxime *anti*-isomer and pralidoxime peaks, *Standard stock solution*

Relative standard deviation: NMT 5.0% for the pralidoxime chloride peak, *Standard solution*

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

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each impurity in the portion of Pralidoxime Chloride taken:

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

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

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

C_S = concentration of [USP Pralidoxime Chloride RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Pralidoxime Chloride in the *Sample solution* (µg/mL)

Acceptance criteria: See [Table 1](#). The reporting level for impurities is 0.05%.

Table 1