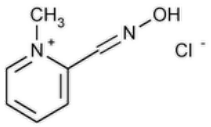
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-05D781B1-3C8F-4D28-A48D-C68EE63C168E_5_en-US
DOI: https://doi.org/10.31003/USPNF_M68220_05_01
DOI Ref: do3p0

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

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Pyridine-2-aldoxime	0.7	0.5
Pralidoxime *anti*-isomer[a]	0.9	2
Pralidoxime	1.0	—
Any other individual impurity	—	0.10
Total impurities	—	3

[a] (*Z*)-2-[(Hydroxyimino)methyl]-1-methylpyridin-1-ium chloride.

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 2.0%

• **Sterility Tests** ⟨71⟩**:** Where the label states that Pralidoxime Chloride is sterile, it meets the requirements.

• **Bacterial Endotoxins Test** ⟨85⟩**:** Where the label states that Pralidoxime Chloride is sterile or must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 0.10 USP Endotoxin Units/mg of pralidoxime chloride.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

• **USP Reference Standards** ⟨11⟩

USP Pralidoxime Chloride RS

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

Topic/Question	Contact	Expert Committee
PRALIDOXIME CHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 42(6)

Current DocID: GUID-05D781B1-3C8F-4D28-A48D-C68EE63C168E_5_en-US

DOI: https://doi.org/10.31003/USPNF_M68220_05_01

DOI ref: do3p0