

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-E153897E-43F9-404B-8DC7-87FC01A47941_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M71980_03_01
 DOI Ref: qs6je

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Pyridostigmine Bromide



$C_9H_{13}BrN_2O_2$ 261.12

Pyridinium, 3-[[[(dimethylamino)carbonyl]oxy]-1-methyl-, bromide;

3-Hydroxy-1-methylpyridinium bromide dimethylcarbamate CAS RN®: 101-26-8; UNII: KVI301NA53.

DEFINITION

Pyridostigmine Bromide contains NLT 98.0% and NMT 102.0% of pyridostigmine bromide ($C_9H_{13}BrN_2O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A or 197K ▲ (CN 1-May-2020)
- **B.** The UV spectrum 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, Bromide*

Sample solution: 20 mg/mL of Pyridostigmine Bromide

Acceptance criteria: Meets the requirements

ASSAY

• PROCEDURE

Buffer: 4.3 g/L of [sodium dodecyl sulfate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (32:68)

System suitability solution: 2 µg/mL each of [USP Pyridostigmine Bromide RS](#), [USP Pyridostigmine Related Compound A RS](#), and [USP Pyridostigmine Related Compound B RS](#) in *Mobile phase*

Standard solution: 0.3 mg/mL of [USP Pyridostigmine Bromide RS](#) in *Mobile phase*

Sample solution: 0.3 mg/mL of Pyridostigmine Bromide in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 2.6 times the retention time of pyridostigmine

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between pyridostigmine related compound A and pyridostigmine, *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 pyridostigmine bromide ($C_9H_{13}BrN_2O_2$) in the portion of Pyridostigmine Bromide 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 Pyridostigmine Bromide RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Pyridostigmine Bromide in the *Sample solution* (mg/mL)

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

IMPURITIES

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

• **ORGANIC IMPURITIES**

Mobile phase and Chromatographic system: Proceed as directed in the Assay.

Sensitivity solution: 0.2 µg/mL of [USP Pyridostigmine Bromide RS](#) in *Mobile phase*

Standard solution: 0.6 µg/mL each of [USP Pyridostigmine Bromide RS](#), [USP Pyridostigmine Related Compound A RS](#), and [USP Pyridostigmine Related Compound B RS](#) in *Mobile phase*

Sample solution: 1000 µg/mL of Pyridostigmine Bromide in *Mobile phase*

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between pyridostigmine related compound A and pyridostigmine, *Standard solution*

Relative standard deviation: NMT 5.0% for all the three peaks, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pyridostigmine related compound A and pyridostigmine related compound B in the portion of Pyridostigmine Bromide taken:

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

r_U = peak response of pyridostigmine related compound A or pyridostigmine related compound B from the *Sample solution*

r_S = peak response of pyridostigmine related compound A or pyridostigmine related compound B from the *Standard solution*

C_S = concentration of [USP Pyridostigmine Related Compound A RS](#) or [USP Pyridostigmine Related Compound B RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Pyridostigmine Bromide in the *Sample solution* (µg/mL)

Calculate the percentage of each unspecified impurity in the portion of Pyridostigmine Bromide 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 pyridostigmine from the *Standard solution*

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

C_U = concentration of Pyridostigmine Bromide in the *Sample solution* (µg/mL)

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.02%.

Table 1