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Pyridostigmine Bromide Injection

» Pyridostigmine Bromide Injection is a sterile solution of Pyridostigmine Bromide in a suitable medium. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_9H_{13}BrN_2O_2$.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass, protected from light.

USP REFERENCE STANDARDS (11)—

[USP Pyridostigmine Bromide RS](#)

Identification—

A: The solution prepared for measurement of absorbance in the Assay exhibits maxima and minima at the same wavelengths as that of a similar solution of [USP Pyridostigmine Bromide RS](#), concomitantly measured.

B: To 2 mL of Injection add 1 mL of 2 N nitric acid: the solution so obtained responds to the tests for [Bromide \(191\)](#).

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 17.0 USP Endotoxin Units per mg of pyridostigmine bromide.

pH (791): between 4.5 and 5.5.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—Transfer to a suitable separator an accurately measured volume of Injection, equivalent to about 20 mg of pyridostigmine bromide. Add 10 mL of 1 N hydrochloric acid, and mix. Extract with four 20-mL portions and one 15-mL portion of ethyl ether, and discard the extracts.

Transfer the aqueous layer to a 100-mL volumetric flask, using about 25 mL of water to aid the transfer. Place the flask on a steam bath and warm, with the aid of a stream of nitrogen, to evaporate any residual ether, then cool the flask to room temperature, dilute with water to volume, and mix. Dilute 20.0 mL of the resulting solution with 0.1 N hydrochloric acid to 100.0 mL, and mix. Dissolve an accurately weighed quantity of [USP Pyridostigmine Bromide RS](#) in 0.1 N hydrochloric acid to obtain a Standard solution having a known concentration of about 40 μ g per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 269 nm, with a suitable spectrophotometer, using 0.1 N hydrochloric acid as the blank. Calculate the quantity, in mg, of $C_9H_{13}BrN_2O_2$ in each mL of the

Injection taken by the formula:

$$(0.5C/V)(A_u/A_s)$$

in which C is the concentration, in μ g per mL, of [USP Pyridostigmine Bromide RS](#) in the Standard solution, V is the volume, in mL, of Injection taken, and A_u and A_s are the absorbances of the solution from the Injection and the Standard solution, respectively.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PYRIDOSTIGMINE BROMIDE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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