

Pyridostigmine Bromide Oral Solution

» Pyridostigmine Bromide Oral Solution contains, in each 100 mL, not less than 1.08 g and not more than 1.32 g of pyridostigmine bromide ($C_9H_{13}BrN_2O_2$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP REFERENCE STANDARDS (11).—

[USP Pyridostigmine Bromide RS](#)

Identification—To 5 mL of Oral Solution in a separator add 100 mL of 2.5 N hydrochloric acid, and mix. Extract with five 20-mL portions of chloroform, place 2 mL of the aqueous solution in a 50-mL volumetric flask, and add water to volume: the UV absorption spectrum of this solution exhibits maxima and minima at the same wavelengths as that of a similar solution of [USP Pyridostigmine Bromide RS](#), concomitantly measured.

Assay—

Phosphate solution—Dissolve 38 g of monobasic sodium phosphate and 2 g of anhydrous dibasic sodium phosphate in water to make 1000 mL. Adjust the pH, if necessary, by slight variation of the ratio of the two ingredients, to 5.3 ± 0.1 .

Bromocresol green solution—Dissolve 250 mg of bromocresol green sodium salt in 250 mL of *Phosphate solution*.

Standard preparation—Dissolve a suitable quantity of [USP Pyridostigmine Bromide RS](#), accurately weighed, in water, to obtain a solution having a known concentration of about 1.2 mg per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 120 mg of pyridostigmine bromide, to a 100-mL volumetric flask, add water to volume, and mix.

Procedure—Transfer 10 mL each, accurately measured, of the *Assay preparation* and the *Standard preparation* to separate 125-mL separators. Into each separator pipet 10 mL of water, 20 mL of *Phosphate solution*, and 5 mL of *Bromocresol green solution*. Extract each solution with six 15-mL portions of chloroform, collecting the chloroform extracts in respective 100-mL volumetric flasks, then add chloroform to volume in each flask, and mix. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 415 nm, with a suitable spectrophotometer, using chloroform as the blank. Calculate the quantity, in mg, of pyridostigmine bromide ($C_9H_{13}BrN_2O_2$) in the portion of Oral Solution taken by the formula:

$$100C(A_u/A_s)$$

in which *C* is the concentration, in mg per mL, of [USP Pyridostigmine Bromide RS](#) in the *Standard preparation*; and *A_u* and *A_s* are the absorbances of the solutions obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
PYRIDOSTIGMINE BROMIDE ORAL SOLUTION	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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