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Neostigmine Bromide Tablets

» Neostigmine Bromide Tablets contain not less than 93.0 percent and not more than 107.0 percent of the labeled amount of $C_{12}H_{19}BrN_2O_2$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Neostigmine Bromide RS

Identification—Extract a quantity of powdered Tablets, equivalent to about 300 mg of neostigmine bromide, with three 10-mL portions of alcohol, filtering after each extraction. Evaporate the combined filtrates under a stream of nitrogen to dryness. Dissolve the residue in 10 mL of water, transfer to a 125-mL separator with the aid of 5 mL of water, extract with 15 mL of ether, and proceed with the following tests.

A: Evaporate 3 mL of the aqueous layer on a steam bath, under a stream of nitrogen, to dryness. Dissolve the residue, warming if necessary, in 1 mL of alcohol. Add 5 mL of chloroform, filter, evaporate the filtrate under a stream of nitrogen to dryness, and dry the residue at 105° for 30 minutes: the IR absorption spectrum of a potassium bromide dispersion of the residue of neostigmine bromide so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Neostigmine Bromide RS.

B: A portion of the aqueous layer responds to the tests for *Bromide* ⟨191⟩.

Dissolution, *Procedure for a Pooled Sample* ⟨711⟩—

Medium: water; 500 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—At the specified time interval, withdraw 30 mL of the solution under test, and filter. Pipet 10 mL each of the filtered test solution, a Standard solution having a known concentration of USP Neostigmine Bromide RS, and water to provide a blank, into respective 125-mL separators. Proceed as directed for *Procedure* in the *Assay*, beginning with "Add 15 mL of a solution."

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{12}H_{19}BrN_2O_2$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Standard preparation—Dissolve a suitable quantity of USP Neostigmine Bromide RS, accurately weighed, in water, and dilute quantitatively and stepwise with water to obtain a solution having a concentration of about 40 µg per mL.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of neostigmine bromide, to a 100-mL volumetric flask, add about 50 mL of water, shake by mechanical means for about 30 minutes, add water to volume, mix, and filter. Pipet 4 mL of the clear filtrate into a 50-mL volumetric flask, add water to volume, and mix.

Procedure—Pipet 10 mL each of *Assay preparation* and *Standard preparation* into respective 125-mL separators, and treat each solution as follows. Add 15 mL of a solution prepared by dissolving 25 mg of hexanitrodiphenylamine in methylene chloride to make 250 mL, without grinding the solid or heating the solution. Then add 10 mL of 5 N sodium hydroxide, and shake vigorously for 30 seconds. Collect the methylene chloride layer in a 100-mL volumetric flask, and extract the aqueous layer with three 15-mL portions of methylene chloride, collecting the methylene chloride extracts in each respective flask. Add methylene chloride to volume, and mix. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 420 nm, with a suitable spectrophotometer, using methylene chloride as the blank. Calculate the quantity, in mg, of $C_{12}H_{19}BrN_2O_2$ in the portion of Tablets taken by the formula:

$$1.25C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Neostigmine Bromide RS in the *Standard preparation*, and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

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

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