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Neostigmine Methylsulfate Injection

» Neostigmine Methylsulfate Injection is a sterile solution of Neostigmine Methylsulfate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{13}H_{22}N_2O_6S$.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, protected from light.

USP REFERENCE STANDARDS (11)—
[USP Neostigmine Methylsulfate RS](#)

Identification—Transfer a volume of Injection, containing the equivalent of 1 mg of neostigmine methylsulfate, to a small porcelain dish. Evaporate, if necessary, to 2 mL, add 0.5 mL of sodium hydroxide solution (2 in 5), and proceed as directed in [Identification](#) test [B](#) under [Neostigmine Methylsulfate](#), beginning with “evaporate on a steam bath.”
pH (791): between 5.0 and 6.5.

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

Assay—

Standard preparation—Dissolve a suitable quantity of [USP Neostigmine Methylsulfate RS](#), accurately weighed, in water, and dilute quantitatively and stepwise with water to obtain a solution having a known concentration of about 40 µg per mL.
Assay preparation—Pipet an accurately measured volume of Injection, equivalent to about 2 mg of neostigmine methylsulfate, into a 50-mL volumetric flask, add water to volume, and mix.
Procedure—Proceed as directed for [Procedure](#) in the [Assay](#) under [Neostigmine Bromide Tablets](#). Calculate the quantity, in mg, of $C_{13}H_{22}N_2O_6S$ in each mL of the Injection taken by the formula:

$$0.05(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of [USP Neostigmine Methylsulfate RS](#) in the *Standard preparation*, V is the volume, in mL, of Injection taken, and A_U and A_S are the absorbances of the solutions 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
NEOSTIGMINE METHYLSULFATE 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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