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Thimerosal Topical Solution

DEFINITION
Thimerosal Topical Solution contains, in each 100 mL, NLT 95 mg and NMT 105 mg of thimerosal ($C_9H_9HgNaO_2S$).

[Note—Thimerosal Topical Solution is sensitive to some metals.]

IDENTIFICATION

• **A.**

Sample: 50 mL of Topical Solution

Analysis 1: Pass hydrogen sulfide through the *Sample*.

Acceptance criteria 1: No black discoloration or black precipitate is formed.

Analysis 2: Add 3 or 4 drops of bromine to the *Sample*, mix, and warm on a steam bath to expel the excess bromine. Add 5 mL of 3 N hydrochloric acid, filter, and pass hydrogen sulfide through the filtrate.

Acceptance criteria 2: A black precipitate is formed.

• **B.**

Sample: 1 mL of Topical Solution

Analysis: To the *Sample* add 9 mL of water, mix, and add 1 mL of cupric sulfate TS.

Acceptance criteria: A green color is produced immediately and is followed by the gradual precipitation of flocculent, greenish brown particles.

ASSAY

• **Procedure**

The *Standard solutions* and *Sample solution* may be diluted with water, if necessary, to yield solutions of suitable concentration, adaptable to the linear or working range of the instrument.

Solution A: Dissolve 50 g of stannous chloride in 100 mL of hydrochloric acid on a steam bath, cool, and dilute with water to 500 mL. Use within 3 months.

Standard stock solution A: 1.8 µg/mL of USP Thimerosal RS

Standard stock solution B: 2.0 µg/mL of USP Thimerosal RS

Standard stock solution C: 2.2 µg/mL of USP Thimerosal RS

Standard solution A: Pipet 20 mL of *Standard stock solution A* into a 100-mL volumetric flask. Add 5 mL of sulfuric acid, cool, add 3 mL of nitric acid, and mix. Add potassium permanganate crystals, while mixing, until the purple color persists for NLT 15 min. Add 200 mg of potassium persulfate, mix, and heat on a steam bath for 2 h. Cool, and dilute with water to volume.

Standard solution B: Pipet 20 mL of *Standard stock solution B* into a 100-mL volumetric flask. Add 5 mL of sulfuric acid, cool, add 3 mL of nitric acid, and mix. Add potassium permanganate crystals, while mixing, until the purple color persists for NLT 15 min. Add 200 mg of potassium persulfate, mix, and heat on a steam bath for 2 h. Cool, and dilute with water to volume.

Standard solution C: Pipet 20 mL of *Standard stock solution C* into a 100-mL volumetric flask. Add 5 mL of sulfuric acid, cool, add 3 mL of nitric acid, and mix. Add potassium permanganate crystals, while mixing, until the purple color persists for NLT 15 min. Add 200 mg of potassium persulfate, mix, and heat on a steam bath for 2 h. Cool, and dilute with water to volume.

Sample stock solution: Pipet 2 mL of Topical Solution into a 1000-mL volumetric flask, and dilute with water to volume.

Sample solution: Pipet 20 mL of *Sample stock solution* into a 100-mL volumetric flask. Add 5 mL of sulfuric acid, cool, add 3 mL of nitric acid, and mix. Add potassium permanganate crystals, while mixing, until the purple color persists for NLT 15 min. Add 200 mg of potassium persulfate, mix, and heat on a steam bath for 2 h. Cool, and dilute with water to volume.

Instrumental conditions

Mode: Flameless atomic absorption spectroscopy

Lamp: Mercury hollow-cathode

Blank solution: Pipet 20 mL of water into a 100-mL volumetric flask. Add 5 mL of sulfuric acid, cool, add 3 mL of nitric acid, and mix. Add potassium permanganate crystals, while mixing, until the purple color persists for NLT 15 min. Add 200 mg of potassium persulfate, mix,

and heat on a steam bath for 2 h. Cool, and dilute with water to volume.

Analysis

Samples: *Standard solutions A, B*, and *C*, *Sample solution*, and *Blank solution*

Proceed with each of the *Samples* as follows. Pipet 3 mL into the scrubbing chamber of a suitable system designed for determination of mercury. Dilute with water to 150 mL, and add hydroxylamine hydrochloride solution (1 in 10) to reduce the excess permanganate. Add 5 mL of *Solution A*, and immediately attach the scrubbing chamber to the system. Concomitantly determine the absorbance of each solution at an integration time of 15 s. Use the absorbance of the *Blank solution* to correct the absorbances of *Standard solutions A, B*, and *C*, and the *Sample solution*. Plot the corrected absorbances of the standards versus their respective concentrations of the *Standard stock solutions*, in µg/mL, and from the curve so obtained, determine the concentration, *C*, in µg/mL, of the *Sample solution*.

Calculate the quantity, in mg, of thimerosal ($C_9H_9HgNaO_2S$) in each 100 mL of Topical Solution taken:

$$\text{Result} = C \times D \times V \times F$$

C = measured concentration of the *Sample solution* (µg/mL)

D = dilution of the *Sample stock solution*, 500

V = volume of Topical Solution, 100 mL

F = unit conversion, 1 mg/1000 µg

Acceptance criteria: 95–105 mg

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 9.6–10.2

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.

• **USP Reference Standards** ⟨11⟩

USP Thimerosal RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
THIMEROSAL TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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