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Thimerosal Tincture

DEFINITION
Thimerosal Tincture contains, in each 100 mL, NLT 90 mg and NMT 110 mg of thimerosal ($C_9H_9HgNaO_2S$).

[Note—Thimerosal Tincture is sensitive to some metals.]

IDENTIFICATION

• **A.**

Sample: 25 mL of Tincture

Analysis: Heat the *Sample* on a steam bath until the odors of alcohol and acetone are no longer perceptible. Cool and pass hydrogen sulfide through the solution.

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

• **B.**

Sample: 50 mL of Tincture

Analysis: Evaporate the *Sample* on a steam bath to a volume of approximately 20 mL, cool, and add 3 or 4 drops of bromine. Add 5 mL of 3 N hydrochloric acid, filter, and pass hydrogen sulfide through the filtrate.

Acceptance criteria: A black precipitate is formed.

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, dilute with water to 500 mL, and mix. 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 Tincture 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. Separately 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 the vapor from 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 the 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 Tincture 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 Tincture, 100 mL

F = unit conversion, 1 mg/1000 µg

Acceptance criteria: 90–110 mg

SPECIFIC TESTS

• **Alcohol Determination,** *Method II*⟨611⟩**:** 45.0%–55.0% of C_2H_5OH

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 TINCTURE	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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