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Hexachlorophene Liquid Soap

DEFINITION

Hexachlorophene Liquid Soap is a solution of Hexachlorophene in a 10.0%–13.0% solution of a potassium soap. It contains, in each 100 g, NLT 225 mg and NMT 260 mg of hexachlorophene ($C_{13}H_6Cl_6O_2$). It may contain suitable water hardness controls.

[NOTE—The inclusion of nonionic detergents in Hexachlorophene Liquid Soap in amounts greater than 8% on a total weight basis may decrease the bacteriostatic activity of the Liquid Soap.]

IDENTIFICATION

- **A.**

  Sample: 2 g

  Analysis: Pour the *Sample* into a beaker, and add, with stirring, dilute hydrochloric acid (1 in 100) until the mixture is just acid to litmus. To 10 mL of the mixture, in a beaker, add 10 mL of chloroform. Add 3 or 4 drops of ferric chloride TS, and allow to stand.

  Acceptance criteria: The chloroform layer becomes purple.

- **B.**

  Sample: 2 mL of the mixture prepared in *Identification* test *A*, in a test tube

  Analysis: Add 2 mL of acetone to the *Sample*. Add 1 mL of titanium trichloride solution (1 in 5), and shake vigorously.

  Acceptance criteria: A yellow oil separates.

ASSAY

- **PROCEDURE**

  Alkaline buffer: Dissolve 6.07 g of tris(hydroxymethyl)aminomethane in 900 mL of methanol. Add 25.0 mL of dilute hydrochloric acid (1 in 10), and dilute with water to 1 L.

  Solution A: Nominally 0.25 mg/mL of hexachlorophene prepared as follows. Transfer a portion of Liquid Soap containing the equivalent of about 100 mg of hexachlorophene to a 100-mL volumetric flask, and add alcohol to volume. Transfer 25.0 mL of this solution to a 100-mL volumetric flask, add 90% methanol to volume, and filter if necessary.

  Control: Add 10.0 mL of *Solution A* to a 50-mL volumetric flask, and fill to volume with 0.3 M acetic acid in 90% methanol containing 0.1% of hydrochloric acid.

  Standard solution: Transfer 50 mg of USP Hexachlorophene RS to a 100-mL volumetric flask, dissolve in 10 mL of alcohol, and dilute with *Alkaline buffer* to volume. Preserve in a tight container.

  Standard hexachlorophene solutions: To 50-mL volumetric flasks add, by pipet and in duplicate, 2-, 3-, 4-, 5-, 6-, and 7-mL portions of the *Standard solution*. To one flask of each pair of duplicates, add to volume acidified 90% methanol containing, in each 100 mL, 5 mL of acetic acid and 0.3 mL of hydrochloric acid. To the second flask of each pair, add *Alkaline buffer* to volume. Arrange the two series of standard hexachlorophene solutions in pairs according to their hexachlorophene content.

  Sample solution: Add 10.0 mL of *Solution A* to a 50-mL volumetric flask, and fill with *Alkaline buffer* to volume.

  Blank: Corresponding acid solution from *Standard hexachlorophene solutions*

  Instrumental conditions

    Mode: UV

    Analytical wavelength: 312 nm

  Analysis

    Samples: *Control*, *Standard hexachlorophene solutions*, *Sample solution*, and *Blank*

      Determine the absorbance of the *Standard hexachlorophene solutions*, using the corresponding concentration of acid solution as the *Blank*. Plot the observed absorbance scale against the corresponding concentration of hexachlorophene, in mg/100 mL, on the abscissa scale.

      Determine the absorbance of the *Sample solution*, using the *Control* as the blank. From the observed absorbance, calculate the weight of hexachlorophene in the Liquid Soap taken.

Acceptance criteria: 225–260 mg of hexachlorophene in each 100 g

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

• **Water Determination,** *Method II* **⟨921⟩**

Sample: 5 g

Analysis: Place the *Sample*, quickly weighed to the nearest centigram, in the distilling flask of the apparatus described in the chapter. The Liquid Soap is most conveniently weighed in a boat of metal foil, of a size that will just pass through the neck of the flask. Place 250 mL of toluene and 10 g of anhydrous barium chloride in the flask, connect the flask through a ground-glass joint to the distilling apparatus, fill the receiving tube with toluene, and determine the water as directed, beginning with "Heat the flask gently".

Acceptance criteria: The volume of water found corresponds to between 86.5% and 90.0% by weight of the portion of Liquid Soap taken.

• **Alcohol-Insoluble Substances**

Sample: 5 g

Analysis: Place the *Sample*, quickly weighed, in 100 mL of hot neutralized alcohol. Dissolve and collect the residue, if any, on a tared filter, thoroughly wash it with hot neutralized alcohol, and dry at 105° for 1 h. Retain this solution and the residue for use in the tests for *Free Alkali Hydroxides* and *Alkali Carbonates*.

Acceptance criteria: The weight of the residue obtained does not exceed 3.0% of the weight of Liquid Soap taken.

• **Free Alkali Hydroxides**

Sample solution: To the combined filtrate and washings obtained in the test for *Alcohol-Insoluble Substances* add 0.5 mL of phenolphthalein TS.

Analysis: If a pink color is produced, titrate the solution with 0.1 N sulfuric acid VS until the pink color is just discharged. Each mL of 0.1 N sulfuric acid is equivalent to 5.61 mg of potassium hydroxide (KOH).

Acceptance criteria: The volume of 0.1 N sulfuric acid consumed corresponds to NMT 0.05% of potassium hydroxide (KOH).

• **Alkali Carbonates**

Sample solution: Wash the filter containing the alcohol-insoluble substances from the *Alcohol-Insoluble Substances* test with 50 mL of boiling water, cool, and add methyl orange TS.

Analysis: Titrate the filtrate with 0.1 N sulfuric acid VS.

Acceptance criteria: NMT 0.5 mL of 0.1 N sulfuric acid per g of Liquid Soap originally taken is required [0.35% calculated as potassium carbonate (K_2CO_3)].

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **Labeling:** Solutions of higher concentrations of hexachlorophene and potassium soap, in which the ratios of these components are consistent with the official limits, may be labeled "For the preparation of Hexachlorophene Liquid Soap, USP", provided that the label indicates that the Liquid Soap is a concentrate and that directions are given for dilution to the official strength.

• **USP Reference Standards ⟨11⟩**

USP Hexachlorophene RS

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

Topic/Question	Contact	Expert Committee
HEXACHLOROPHENE LIQUID SOAP	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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

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