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Lindane Cream

DEFINITION

Lindane Cream is Lindane in a suitable cream base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of lindane (γ-$C_6H_6Cl_6$).

IDENTIFICATION

• **A.**

Analysis: Wind a strip of 20-mesh copper gauze 1.5 cm wide and 5 cm long around the end of a copper wire. Heat the gauze in the nonluminous flame of a Bunsen burner until it glows without coloring the flame green. Allow the gauze to cool, and repeat the heating and cooling step several times until a thorough coating of oxide is formed. Apply a small amount of Cream to the cooled gauze, ignite, and allow to burn freely in the air. Hold the gauze in the outer edge of the burner flame at a height of 4 cm.

Acceptance criteria: A bright green color is imparted to the flame.

ASSAY

• **Procedure**

Mobile phase: Mix 18 mL of anhydrous ethyl ether with 280 mL of chromatographic hexane.

Internal standard solution: 1 mg/mL of *n*-docosane in methylene chloride

Standard stock solution: 2 mg/mL of USP Lindane RS in methylene chloride

Standard solution: Transfer 5.0 mL of *Standard stock solution* to a graduated centrifuge tube, add 5.0 mL of *Internal standard solution*, and evaporate with the aid of gentle heat and a current of dry air to 3 mL. Avoid evaporating to dryness. If the mixture is inadvertently evaporated to dryness, discard it, and begin another *Standard solution*.

Solid support: 60- to 100-mesh magnesium silicate that has been heated previously at 300° for 2 h

Sample stock solution: Nominally 2 mg/mL of lindane from a quantity of Cream, equivalent to 10 mg of lindane, prepared as follows. Place a pledget of cotton on a removable porous plate at the base of a 25-mm × 200-mm chromatographic tube fitted with a polytef stopcock. Add 50 mL of *Mobile phase* and 10 g of *Solid support*, and stir the mixture to expel air bubbles. Add 1.5 g of anhydrous sodium sulfate to the column, and elute until the surface of the liquid is 4 cm above the *Solid support*, discarding the eluate. Transfer a portion of Cream to a 150-mL beaker, and add 10 g of *Solid support*. Mix with a spatula, adding chromatographic hexane as necessary to produce a homogeneous mixture, and continue stirring until a free-flowing powder is produced. Transfer this mixture to the chromatographic column with the aid of three 5-mL portions of *Mobile phase*, and elute the column with 225 mL of the *Mobile phase* at a flow rate of 2–3 mL/min, collecting the eluate in a 250-mL beaker. Remove the chromatographic column, add 5.0 mL of *Internal standard solution* to the eluate, and evaporate with the aid of gentle heat and a current of dry air to 5 mL.

Sample solution: Transfer the *Sample stock solution* to a graduated centrifuge tube with the aid of 1 mL of methylene chloride, and evaporate with the aid of gentle heat and a current of dry air to 3 mL. Avoid evaporating to dryness. If the mixture is inadvertently evaporated to dryness, discard it, and begin another *Sample solution*.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 1.8-m × 2-mm glass; packed with 3% liquid phase G3 on support S1A

Temperatures

Column: 195°

Injection port: 250°

Detector: 250°

Flow rate: 40 mL/min

Injection volume: 1 µL

Carrier gas: Dry nitrogen

System suitability

Sample: *Standard solution* (6–10 replicate injections)

Suitability requirements

Resolution: NLT 5 between lindane and *n*-docosane

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lindane (γ-$C_6H_6Cl_6$) in the portion of Cream taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of lindane to *n*-docosane in the *Sample solution*

R_S = peak response ratio of lindane to *n*-docosane in the *Standard solution*

C_S = concentration of USP Lindane RS in the *Standard stock solution* (mg/mL)

C_U = nominal concentration of lindane in the *Sample stock solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: 1-in-5 dilution

Acceptance criteria: 8.0–9.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Lindane RS

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

Topic/Question	Contact	Expert Committee
LINDANE CREAM	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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