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Lindane Shampoo

DEFINITION

Lindane Shampoo is Lindane in a suitable vehicle. It contains NLT 90.0% and NMT 110.0% of the labeled amount of lindane ($\gamma\text{-C}_6\text{H}_6\text{Cl}_6$).

IDENTIFICATION

• **A.**

Analysis: Wind a 1.5-cm × 5-cm strip of 20-mesh copper gauze 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 Shampoo 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.

Add the following:

▲ **B.** The retention time of the lindane peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲

(USP 1-Aug-2022)

ASSAY

Change to read:

• **PROCEDURE**

▲ **Diluent:** [Methylene chloride](#) and [methanol](#) (80:20)

Internal standard solution: 0.025 mg/mL of 1-chloro-4-nitrobenzene in [acetonitrile](#)

Standard stock solution: 0.25 mg/mL of [USP Lindane RS](#) in *Diluent*

Standard solution: 0.01 mg/mL of [USP Lindane RS](#) in *Internal standard solution*, from *Standard stock solution*

Sample stock solution: Nominally 0.25 mg/mL of lindane in *Diluent* prepared as follows. Accurately weigh and transfer a portion of Shampoo to a suitable volumetric flask. Add about 80% of the final flask volume of *Diluent*. Shake on a shaker to combine and dilute with *Diluent* to volume.

Sample solution: 0.01 mg/mL of lindane in *Internal standard solution*, from *Sample stock solution*. Centrifuge the suspension, and pass the supernatant through a suitable filter of 0.45-μm pore size.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC

Detector: Electron capture

Column: 0.53-mm × 30-m fused-silica; coated with a 1-μm film of phase [G27](#)

Temperatures

Injection port: 220°

Detector: 300°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
180	0	180	2
180	10	280	13

Carrier gas: Nitrogen

Flow rate: 2.0 mL/min

Makeup flow: 30 mL/min

Injection volume: 1 μL

Injection type: Split, split ratio 30:1

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for 1-chloro-4-nitrobenzene and lindane are about 0.5 and 1.0, respectively.]

Suitability requirements

Tailing factor: NMT 2.0 for lindane

Relative standard deviation: NMT 2.0% of the peak response ratio of lindane to 1-chloro-4-nitrobenzene

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lindane ($\gamma\text{-C}_6\text{H}_6\text{Cl}_6$) in the portion of Shampoo taken:

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

R_U = peak response ratio of lindane to 1-chloro-4-nitrobenzene from the *Sample solution*

R_S = peak response ratio of lindane to 1-chloro-4-nitrobenzene from the *Standard solution*

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

C_U = nominal concentration of lindane in the *Sample solution* (mg/mL)▲ (USP 1-Aug-2022)

Acceptance criteria: 90.0%–110.0%

Add the following:

▲**IMPURITIES**

• **ORGANIC IMPURITIES**

Standard solution: 0.002 mg/mL each of [USP Lindane RS](#) and [USP Lindane Related Compound A RS](#) in [cyclohexane](#). Sonicate to dissolve, if necessary. Centrifuge a portion of the solution, and use the clear supernatant. [NOTE—Centrifuging at 1000 rpm for 10 min may be suitable.]

Sample solution: Nominally 0.2 mg/mL of Lindane in [cyclohexane](#) prepared as follows. Shake the sample gently for 1 min. Transfer about 1 g of lindane shampoo to a 50-mL volumetric flask. Add 40 mL of [cyclohexane](#), and shake vigorously until the Shampoo is dispersed. Dilute with [cyclohexane](#) to volume. Centrifuge a portion of the solution, and use the clear supernatant. [NOTE—Centrifuging at 1000 rpm for 10 min may be suitable.]

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC

Detector: Electron capture

Column: 0.53-mm × 15-m fused-silica; coated with a 1-μm film of phase [G3](#)

Temperatures

Injection port: 240°

Detector: 300°

Column: See [Table 2](#).

Table 2

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
180	0	180	12
180	20	240	3

Carrier gas: Helium

Linear velocity: 37 cm/s

Makeup gas: Nitrogen

Makeup flow: 25 mL/min

Injection volume: 1 μL

Injection type: Split, split ratio 40:1

System suitability

Sample: *Standard solution*

[NOTE—See [Table 3](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 2 between lindane and lindane related compound A

Tailing factor: NMT 2 for lindane related compound A

Relative standard deviation: NMT 10% for lindane related compound A

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Shampoo taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of [USP Lindane Related Compound A RS](#) from the *Standard solution*

C_S = concentration of [USP Lindane Related Compound A RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: See [Table 3](#). The reporting threshold is 0.05%.

Table 3

Name	Relative Retention Time	Acceptance Criteria, NMT(%)
Pentachlorocyclohexene ^a	0.29	0.8
Lindane related compound A	0.74	1.0
Lindane	1.00	—
Any individual, unspecified impurity	—	0.2
Total impurities	—	1.5▲ (USP 1-Aug-2022)

^a 1,3,4,5,6-pentachlorocyclohex-1-ene.

SPECIFIC TESTS

- [pH \(791\)](#): 6.2–7.0

ADDITIONAL REQUIREMENTS

Change to read:

- **PACKAGING AND STORAGE:** Preserve in tight containers. ▲Store at controlled room temperature.▲ (USP 1-Aug-2022)

Change to read:

- [USP REFERENCE STANDARDS \(11\)](#).
[USP Lindane RS](#)

▲ [USP Lindane Related Compound A RS](#)

α-Hexachlorocyclohexane;
(1R,2R,3R,4R,5S,6S)-1,2,3,4,5,6-Hexachlorocyclohexane.
 $C_6H_6Cl_6$ 290.83▲ (USP 1-Aug-2022)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
LINDANE SHAMPOO	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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