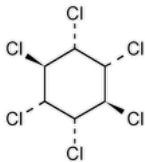


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Lindane

Change to read:



$C_6H_6Cl_6$ 290.83
Cyclohexane, 1,2,3,4,5,6-hexachloro-, (1 α ,2 α ,3 β ,4 α ,5 α ,6 β)-;
 γ -1,2,3,4,5,6-Hexachlorocyclohexane;
 $\blacktriangle$ (1R,2r,3S,4R,5r,6S)-1,2,3,4,5,6-Hexachlorocyclohexane $\blacktriangle$ (USP 1-Aug-2022) CAS RN[®]: 58-89-9; UNII: 59NEE7PCAB.

DEFINITION
Lindane is the gamma isomer of hexachlorocyclohexane. It contains NLT 99.0% and NMT 101.0% of lindane (γ -C₆H₆Cl₆).

IDENTIFICATION

Change to read:

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K $\blacktriangle$ or 197A $\blacktriangle$ (USP 1-Aug-2022)

Add the following:

- $\blacktriangle$ • **B.** The retention time of the lindane peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. $\blacktriangle$
(USP 1-Aug-2022)

ASSAY

Change to read:

• **PROCEDURE**

$\blacktriangle$ **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: 0.25 mg/mL of Lindane in *Diluent*
Sample solution: 0.01 mg/mL of Lindane in *Internal standard solution*, from *Sample stock solution*

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

Mode: GC
Detector: Electron capture
Column: 0.53-mm $\times$ 30-m fused-silica; coated with a 1- μ m 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 1.0% of the peak response ratio of lindane to 1-chloro-4-nitrobenzene

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of lindane ($\gamma\text{-C}_6\text{H}_6\text{Cl}_6$) in the portion of Lindane 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 = concentration of Lindane in the *Sample solution* (mg/mL)▲ (USP 1-Aug-2022)

Acceptance criteria: 99.0%–101.0%

IMPURITIES

• **CHLORIDE ION**

Sample: 100 mg of Lindane

Analysis: Place the *Sample* in a test tube with 10 mL of [water](#), shake, and filter. Add 1 mL of [nitric acid](#) and 3 mL of [silver nitrate TS](#) to the filtrate.

Acceptance criteria: No turbidity develops.

Add the following:

▲• **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: 0.2 mg/mL of Lindane 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.]

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 15% for lindane related compound A

Analysis

Samples: *Standard solution* and *Sample solution*
Calculate the percentage of each impurity in the portion of Lindane taken:

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 = 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 (%)
Lindane related compound A	0.93	1.0
Lindane	1.00	—
Any individual, unspecified impurity	—	0.10
Total impurities	—	1.0▲ (USP 1-Aug-2022)

SPECIFIC TESTS

- [CONGEALING TEMPERATURE \(651\)](#): NLT 112.0°
- [WATER DETERMINATION \(921\), Method I](#): NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Change to read:

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

▲ [USP Lindane Related Compound A RS](#)
α-Hexachlorocyclohexane;
Also known as (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	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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