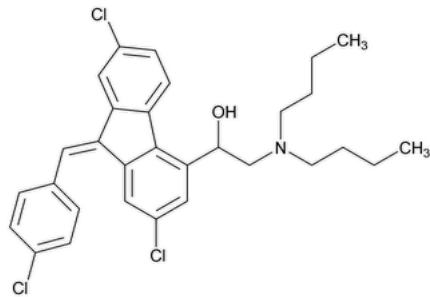


Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Sep-2021
Document Type: USP Monographs
DocId: GUID-52B5556E-6846-4833-BB23-DB756AE4C435_5_en-US
DOI: https://doi.org/10.31003/USPNF_M4854_05_01
DOI Ref: hw8az

© 2025 USPC
Do not distribute

Lumefantrine

Change to read:



$C_{30}H_{32}Cl_3NO$ 528.94
(±)-2,7-Dichloro-9-[(Z)-p-chlorobenzylidene]-α-[(dibutylamino)methyl]-fluorene-4-methanol CAS RN®: 82186-77-4; UNII: F38R0JR742.

DEFINITION

Lumefantrine contains NLT 98.0% and NMT 102.0% of lumefantrine ($C_{30}H_{32}Cl_3NO$).

IDENTIFICATION

- A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)
- B. The retention time of the lumefantrine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: Dissolve 5.65 g of sodium 1-hexanesulfonate and 2.75 g of monobasic sodium phosphate in 900 mL of water. Adjust with phosphoric acid to a pH of 2.3 before dilution with water to a final volume of 1000 mL.

Solution A: Acetonitrile and *Buffer* (300:700)

Solution B: Acetonitrile and 2-propanol (540:460)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	65	35
1.2	65	35
6.0	50	50
6.4	30	70
10.0	25	75
15.0	10	90
15.1	65	35
20.0	65	35

System suitability stock solution: 10 µg/mL of [USP Lumefantrine Related Compound A RS](#) prepared as follows. Transfer a suitable quantity of [USP Lumefantrine Related Compound A RS](#) to a volumetric flask, dissolve in 10% volume dichloromethane, and dilute with acetonitrile to volume.

System suitability solution: 1 mg/mL of [USP Lumefantrine RS](#) and 1 µg/mL of [USP Lumefantrine Related Compound A RS](#) prepared as follows. Transfer 10 mg of [USP Lumefantrine RS](#) to a 10-mL volumetric flask, and dissolve in 1 mL of dichloromethane. Add 1.0 mL of the *System suitability stock solution*, and dilute with acetonitrile to volume.

Standard solution: 1 mg/mL of [USP Lumefantrine RS](#) prepared as follows. Transfer a suitable quantity of [USP Lumefantrine RS](#) to a volumetric flask, dissolve in 10% volume of dichloromethane, and dilute with acetonitrile to volume.

Sample solution: 1 mg/mL of Lumefantrine prepared as follows. Transfer a suitable quantity of Lumefantrine to a volumetric flask, dissolve in 10% volume of dichloromethane, and dilute with acetonitrile to volume.

Chromatographic system

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

Mode: LC

Detector: UV 265 nm

Column: 4.6-mm × 50-mm; 1.8-µm packing L1

Column temperature: Beginning of column, 50°; end of column, 35°

Flow rate: 2.5 mL/min

Injection volume: 2.5 µL

Run time: 20 min

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for lumefantrine related compound A and lumefantrine are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.3 between lumefantrine and lumefantrine related compound A, *System suitability solution*

Tailing factor: NMT 2.1, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of lumefantrine ($C_{30}H_{32}Cl_3NO$) in the portion of Lumefantrine taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0%

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

• **ORGANIC IMPURITIES**

Buffer, Solution A, Solution B, Mobile phase, System suitability stock solution, System suitability solution, Sample solution,

Chromatographic system, and **System suitability:** Proceed as directed in the Assay.

Standard stock solution: 50 µg/mL of [USP Lumefantrine RS](#) prepared as follows. Transfer a suitable quantity of [USP Lumefantrine RS](#) into a volumetric flask, dissolve in 10% volume of dichloromethane, and dilute with acetonitrile to volume.

Standard solution: 1 µg/mL of [USP Lumefantrine RS](#) in acetonitrile from the *Standard stock solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of desbutyl lumefantrine or any other impurity in the portion of Lumefantrine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of desbutyl lumefantrine or any other impurity from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

F = relative response factor

Acceptance criteria: See [Table 2](#). Disregard any peak less than 0.05%.

Table 2