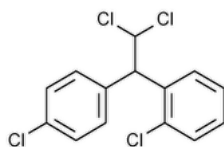


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Mitotane

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-mitotane-20230728.



$C_{14}H_{10}Cl_4$ 320.04

Benzene, 1-chloro-2-[2,2-dichloro-1-(4-chlorophenyl)ethyl]-, (RS)-;

(±)-1,1-Dichloro-2-(o-chlorophenyl)-2-(p-chlorophenyl)ethane CAS RN®: 53-19-0; UNII: 78E4J5IB5J..

DEFINITION

Mitotane contains NLT 97.0% and NMT 103.0% of mitotane ($C_{14}H_{10}Cl_4$), calculated on the anhydrous basis.

[CAUTION—Handle Mitotane with exceptional care, because it is a highly potent agent.]

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197M ▲ or 197A ▲ (RB 1-Aug-2023)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• PROCEDURE

Buffer: 1.38 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (75:25)

System suitability solution: 0.2 mg/mL of [USP Mitotane RS](#) and 0.2 mg/mL of ▲ [USP Mitotane Related Compound A RS](#) in *Mobile phase* ▲

(RB 1-Aug-2023)

Standard solution: 0.2 mg/mL of [USP Mitotane RS](#) in *Mobile phase*

Sample solution: 0.2 mg/mL of Mitotane in *Mobile phase*. [NOTE—Inject within 48 h of preparation.]

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—The relative retention times for ▲ mitotane related compound A ▲ (RB 1-Aug-2023) and mitotane are about 0.92 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between ▲ mitotane related compound A ▲ (RB 1-Aug-2023) and mitotane, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mitotane ($C_{14}H_{10}Cl_4$) in the portion of Mitotane taken:

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

r_U = peak response of mitotane from the *Sample solution*

r_S = peak response of mitotane from the *Standard solution*

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

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

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

Delete the following:

- ▲ • **ORGANIC IMPURITIES** ▲ (RB 1-Aug-2023)

SPECIFIC TESTS

- [WATER DETERMINATION \(921\)](#), [Method I](#), [Method Ia](#): NMT 0.5%

ADDITIONAL REQUIREMENTS

Change to read:

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. ▲Store at room temperature.▲ (RB 1-Aug-2023)

Change to read:

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

[USP Mitotane RS](#)

- ▲ [USP Mitotane Related Compound A RS](#)

2,2-Bis(4-Chlorophenyl)-1,1-dichloroethane.

$C_{14}H_{10}Cl_4$

320.04▲ (RB 1-Aug-2023)

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

Topic/Question	Contact	Expert Committee
MITOTANE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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