

Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-Aug-2023
 Document Type: USP Monographs
 DocId: GUID-623FA08F-EE38-4DAF-9980-04489966B603_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M54480_04_01
 DOI Ref: t18eg

© 2025 USPC
 Do not distribute

Mitotane Tablets

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

DEFINITION

Mitotane Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of mitotane ($C_{14}H_{10}Cl_4$).

IDENTIFICATION

• A.

Sample: Triturate a quantity from finely powdered Tablets nominally equivalent to 500 mg of mitotane, with 10 mL of [water](#).

Analysis: Pass through a sintered-glass filter funnel, and wash the residue with two 5-mL portions of [water](#). Transfer the residue to a small beaker, add 4 mL of [alcohol](#), heat to boiling, and filter immediately. Allow the filtrate to cool, filter the crystals of mitotane, wash once with 2 mL of [alcohol](#), and dry in vacuum at 60° for 2 h.

Acceptance criteria: The IR absorption spectrum of a mineral oil dispersion of the *Sample* exhibits maxima only at the same wavelengths as that of a similar preparation of [USP Mitotane RS](#).

Add the following:

▲• B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (RB 1-Aug-2023)

ASSAY

Change to read:

• **PROCEDURE**

▲**Solution A:** [Methanol](#) and [water](#) (90:10)

Solution B: [Methanol](#)

Mobile phase: See [Table 1](#). Return to original conditions, and re-equilibrate the system for 15 min.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
10	0	100
25	0	100

System suitability solution: 5 mg/mL of [USP Mitotane RS](#) and 0.1 mg/mL of [USP Mitotane Related Compound A RS](#) in [methanol](#). Use sonication to aid dissolution.

Standard solution: 5 mg/mL of [USP Mitotane RS](#) in [methanol](#). Use sonication to aid dissolution.

Sample solution: Nominally 5 mg/mL of mitotane in [methanol](#) prepared as follows. Transfer a portion of finely powdered Tablets (NLT 10) into a suitable volumetric flask, dissolve in [methanol](#) by sonication for 1 min and stirring for NLT 10 min. Dilute with [methanol](#) to volume. Pass a portion of the solution through a suitable filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 268 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 and mitotane are about 0.95 and 1.0, respectively.]

Suitability requirements**Resolution:** NLT 0.85 between mitotane and mitotane related compound A, System suitability solution**Relative standard deviation:** NMT 2.0%, Standard solution**Analysis****Samples:** Standard solution and Sample solutionCalculate the percentage of the labeled amount of mitotane ($C_{14}H_{10}Cl_4$) in the portion of Tablets 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 = nominal concentration of mitotane in the Sample solution (mg/mL)

▲ (RB 1-Aug-2023)

Acceptance criteria: 90.0%–110.0%**Delete the following:**▲**IMPURITIES**▲ (RB 1-Aug-2023)**PERFORMANCE TESTS**

- [DISINTEGRATION \(701\)](#)

Time: 15 min, the use of disks being omitted**Acceptance criteria:** Meet the requirements

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS**Change to read:**

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistance containers. ▲Store at controlled 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 TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. 46(4)

Current DocID: [GUID-623FA08F-EE38-4DAF-9980-04489966B603_4_en-US](#)**DOI:** https://doi.org/10.31003/USPNF_M54480_04_01**DOI ref:** [t18eg](#)