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# 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](http://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<sub>14</sub>H<sub>10</sub>Cl<sub>4</sub>).

**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 sonicating 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 solution*Calculate 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	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

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

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