



## Mitotane Tablets

<b>Type of Posting</b>	Revision Bulletin
<b>Posting Date</b>	28-Jul-2023
<b>Official Date</b>	1-Aug-2023
<b>Expert Committee</b>	Small Molecules 3

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Mitotane Tablets monograph.

As part of the USP monograph modernization effort, the Mitotane Tablets monograph was modernized and published in *PF* 46(4). On the basis of comments received from the manufacturers, USP extended the official date from August 1, 2022 to August 1, 2023, which was communicated through a [Notice of Intent to Revise](#).

The purpose of this revision is to delete the *Organic Impurities* test, in which the procedure is not suitable for the analysis of the only marketed product approved by the FDA and the *Acceptance criteria* are not consistent with the FDA-approved specifications. USP intends to publish an additional proposal in the *Pharmacopeial Forum* to add an *Organic Impurities* test that is consistent with the FDA-approved applications.

The Mitotane Tablets Revision Bulletin supersedes the currently official Mitotane Tablets monograph.

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