



Mitotane

Type of Posting	Revision Bulletin
Posting Date	28-Jul-2023
Official Date	1-Aug-2023
Expert Committee	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 monograph.

As part of the USP monograph modernization effort, the Mitotane 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 Revision Bulletin supersedes the currently official Mitotane monograph.

Should you have any questions, please contact Devarshi Thaker, Senior Scientist II (+91-40-4448-8945 or devarshinarendra.t@usp.org).