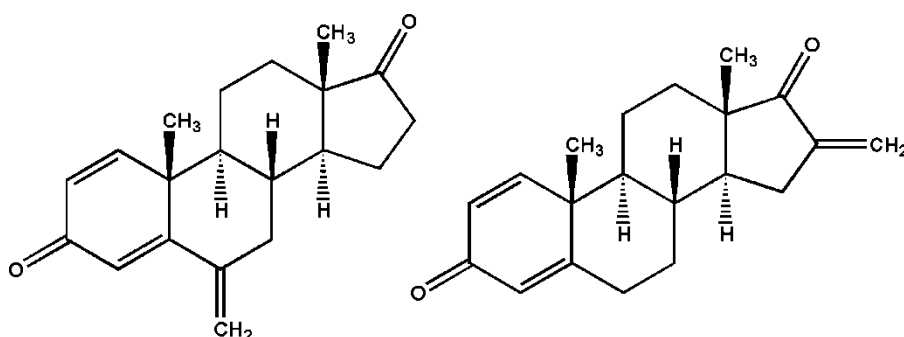




U.S. Pharmacopeia
The Standard of QualitySM

USP Certificate

Exemestane System Suitability Mixture LOT F0J317



Molecular Formula

$C_{20}H_{24}O_2$

Molecular Weight

296.40

CAS Number

N/A

A mixture of Exemestane and Exemestane Related Compound D

LABEL TEXT



Lot No.: F0J317

USP[®] REFERENCE STANDARD

EXEMESTANE SYSTEM SUITABILITY MIXTURE 25 mg

Danger! May damage fertility or the unborn child.

The mixture contains approximately 0.3% of exemestane related compound D in exemestane matrix. Do not dry. Keep container tightly closed. Protect from light. Store in a refrigerator.



USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666

CAT No. 1269094

Material mfd in Taiwan

Intentionally over-labeled for GHS compliance

For use with specified USP compendial tests. Not for use as a drug. See SDS prior to use at www.usp.org/sds.

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. If exposed or concerned: Get medical advice/attention. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.

Jeri L. Joth

QA Director



TYPICAL CHROMATOGRAM

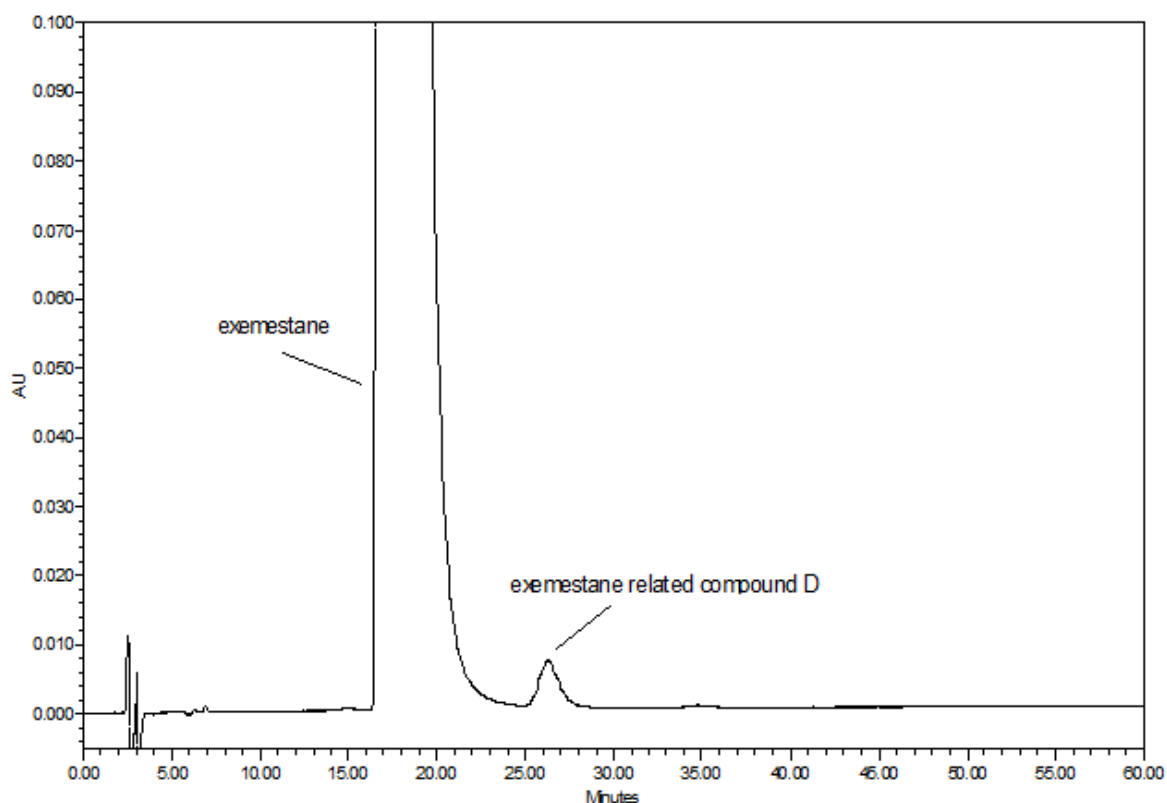
USP Exemestane System Suitability Mixture RS

Lot F0J317 (Cat. No. 1269094)

USP Pending Monograph: Exemestane

Test: Organic Impurities, Procedure ###: Limit of exemestane related compound D

Solution: System suitability solution



This chromatogram is supplied for information only to assist in identifying peaks and does not constitute any legal requirement.

Calculation Value

Unless otherwise stated on the Reference Standard label, a value of 100.0% should be used in the compendial applications for which the use of this Reference Standard is intended. Please refer to the specific Reference Standard label for further information.

Expiration

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at www.usp.org.

Instructions for Use

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

LEGAL NOTICE

USP WARRANTS GOOD TITLE TO USP REFERENCE STANDARDS ON DISPATCH FROM USP. THE FOREGOING WARRANTY IS IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY WARRANTY THAT THE PRODUCTS, INCLUDING THIS CERTIFICATE, ARE OF MERCHANTABLE QUALITY. USP'S LIABILITY ARISING OUT OF OR RELATING TO THE SUPPLY OF USP REFERENCE STANDARDS AND THIS CERTIFICATE SHALL IN NO EVENT INCLUDE LOSS OF PROFITS, COST OF PROCURING SUBSTITUTE GOODS OR SERVICES, OR ANY INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES OF ANY KIND, EVEN IF USP IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, USP DOES NOT WARRANT THAT THE USE OR RESALE OF USP REFERENCE STANDARDS, INCLUDING THEIR USE TO PERFORM TESTS AND ASSAYS PUBLISHED BY USP, WILL NOT INFRINGE UNITED STATES OR ANY OTHER PATENTS.

USP Reference Standards are not intended for use as drugs, dietary supplements, or as medical devices.

This certificate may not be reproduced without the express written permission of USP.

Copyright 2010 The United States Pharmacopeial Convention. All rights reserved.