



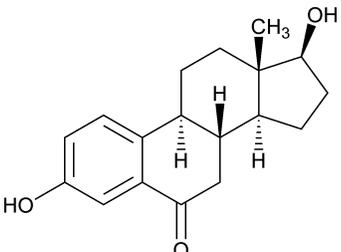
USP REFERENCE STANDARD CERTIFICATE

ESTRADIOL RELATED COMPOUND C

USP Catalog No.: 1250041

USP Lot No.: R22020

Chemical Information

Chemical Name(s):	1,3,5(10)-Estratrien-3,17 β -diol-6 one		
	CAS Number:	571-92-6	
	Molecular Formula:	C ₁₈ H ₂₂ O ₃	
	Molecular Weight:	286.37	

Additional Information

Contains 100 % of estradiol related compound C on the as is basis considering organic impurities by HPLC at 220 nm and water content.

Method Reference: Estradiol Vaginal Inserts, Organic Impurities, USP-NF 2024

This reference standard has no compendial quantitative uses. The value is provided for informational purposes only. Users are responsible for ensuring that the reference standard, including the provided value, is suitable for non-compendial use(s).



USP REFERENCE STANDARD CERTIFICATE

Label

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

REFERENCE STANDARD

ESTRADIOL RELATED COMPOUND C 15 mg

Danger! May cause cancer. May damage fertility or the unborn child.

Keep container tightly closed. Protect from light.

See certificate for any additional information.
 USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
 Cat. No. 1250041 Material mfd. in United States

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.

Lot: R22020

Michelle Osiemmi

Quality Assurance

Certificate Version History

Version Number	Date	Reasons for Change
00 (Current)	15-JUL-2024	First issue



USP REFERENCE STANDARD CERTIFICATE

Label

Reference Standard label typically contains the name, catalog number, lot number, package size, assigned value when applicable, storage conditions, handling instructions, and country of origin information. The label may also include hazard and precautionary statements required by the Occupational Safety and Health Administration (OSHA).

Assigned Value

For USP Reference Standards with compendial quantitative use(s), an assigned value is provided on the label and/or the Certificate.

For USP Reference Standards with compendial qualitative use(s), USP may choose to provide a value, e.g., chromatographic purity, for informational purposes in the Certificate, on a case-by-case basis.

Valid Use Date

It is the responsibility of the user to ascertain that a particular lot of a USP Reference Standard has official status either as a "Current Lot" or as a "Previous Lot" within the assigned valid use date. The online USP Reference Standards Catalog and the online USP Store at www.usp.org are updated daily. USP recommends referring to one of these sources prior to using a USP Reference Standard to make sure the lot is valid for use.

Storage

Storage conditions are lot-specific and may change from one lot to another. Storage conditions on the label and/or the Certificate are valid for unopened container as received. Once the container is opened, unless otherwise specified on the label and/or the Certificate, users are responsible for storing any remaining material according to their site procedures and ensuring continued suitability for its intended use. If no specific directions or limitations are provided on the label, conditions of storage include storage at room temperature and protection from moisture, light, freezing, and excessive heat. See General Chapter <659> in the USP-NF Online for storage and handling definitions.

Instructions for Use

Follow the instructions provided on the label and/or the Certificate and in the associated USP documentary standard(s). Please refer to General Chapter <11> for additional information.

Non-USP Compendial Use

USP Reference Standards are for use in analytical or laboratory applications generally as specified in USP compendia. They are not for use in humans or animals as drugs, food, or medical devices. It may be possible to use a USP RS outside of its associated USP compendial applications; however, it is the responsibility of the user to determine the suitability of the USP RS for a non-USP use.

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 MERCHANTABILITY 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, food, or as medical devices.

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