

# **Certificate**

## **SIROLIMUS**

((35,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)-9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-Hexadecahydro-9,27-dihydroxy-3-[(1R)-2-[(1S,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]-oxaazacyclohentriacontine-1,5,11,28,29(4H,6H,31H)-pentone)

USP Catalog No.: 1612765 USP Lot No.: R193V0



## **LABEL TEXT**





### **REFERENCE STANDARD**

#### SIROLIMUS 50 mg

Danger! Suspected of causing cancer. Suspected of damaging fertility or the unborn child. Causes damage to organs (immune system) through prolonged or repeated exposure.

For quantitative applications, use a value of 0.994 mg of sirolimus per mg of material on the as is basis. Keep container tightly closed. Protect from exposure to oxygen. Protect from light. Store in a freezer.

See certificate for any additional information.
USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
Cat. No. 1612765 Material mfd. in China

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. 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.



Quality Assurance

**Certificate Version History** 

ecitinate version instal		
Version	Date	Reasons for Change
Number		
00	26-SEP-2023	First issue
(Current)		

Copyright 2018 The United States Pharmacopeial Convention. All rights reserved.

**USP** Certificate

USP Template No.: CERT1-07

Template Effective Date: August 31, 2021



#### **Assigned Value**

Please refer to the USP Reference Standard label and/or USP Certificate for the assigned value of the specific lot. Ifan assigned value is not included on the label or Certificate, the lot was developed for qualitative USP compendial use and an assigned value will not be provided.

#### 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 <a href="https://www.usp.org">www.usp.org</a> are updated daily. USP recommends referring to one of these sources prior to using a USP RS to make sure the lot is valid for use.

#### **Storage**

Storage conditions are lot–specific and may change from one lot to another. The storage condition for an unopened USP Reference Standard is provided on the container label only, not on the Safety Data Sheet. If no specific directions or limitations are 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 this Certificate, on the label of the USP Reference Standard, 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 intended only for use in analytical or laboratory applications generally as specified in USP compendia. They are not for use in humans or animals as drugs 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 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 2018 The United States Pharmacopeial Convention. All rights reserved.

**USP** Certificate

USP Template No.: CERT1-07

Template Effective Date: August 31, 2021