

April 13, 2023

RE: USP Everolimus System Suitability Mixture Reference Standard (Catalog # 1268987, Lot R171P0)

Dear USP Customer,

The purpose of this notice is to inform your company that recent evaluation of USP Everolimus System Suitability Mixture Reference Standard (RS), Catalog # 1268987, Lot R171P0 by USP scientific staff has revealed that it is no longer suitable for its compendial uses due to the possibility of an unknown impurity interfering with the resolution between 9-*O*-hydroxyethyl sirolimus and everolimus.

Please discontinue the use of this lot. It has been assigned a Valid Use Date of April 13, 2023.

A new lot is in the early stages of development. An estimated release date is unavailable at this time. As development progresses, the estimated availability date will be updated on the RS's product page in the online USP store (<https://store.usp.org>). We recommend periodically checking this page for updates.

To be notified when the new lot is available, please visit the product page and click on the 'Not Available to Ship, Notify Me When Available' button. You will then be able to opt in to be notified via email when the RS becomes available for shipping. You are also welcome to place an order prior to its release. If the lot is released more than 30 days after your order date then you will first receive a Notice of Availability email to confirm you would like to proceed with processing your order. You can view the status, including the estimated availability date, and manage any items you have ordered that are on backorder directly in your USP Store account (Account Information → Backordered Items).

We are offering our customers the ability to return any unopened vials for credit. Claims for credit must be made within 90 days of the date of this letter. Please contact Customer Service at 1-800-227-8772 or custsvc@usp.org to make necessary arrangements (International customers please call 1-301-881-0666). Please have your order number and photographic evidence for any unopened vials available when you contact USP. We sincerely apologize for any inconvenience this may have caused your company.

For technical questions, please contact Reference Standard Technical Services at rstech@usp.org.

Sincerely,

Quality Assurance Department

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852