

March 12, 2021

RE: USP 4-Epianhydrotetracycline Hydrochloride Reference Standard (Catalog # 1236506, Lot R11400)

Dear USP Customer,

The purpose of this notice is to make you aware that USP 4-Epianhydrotetracycline Hydrochloride Reference Standard (RS), Catalog #1236506, Lot R11400 contains 4.9% of anhydrotetracycline hydrochloride determined by USP scientific staff. This content needs to be considered in the calculation when performing the *Organic Impurities test* in the USP Tetracycline, Tetracycline Hydrochloride, and Tetracycline Hydrochloride Capsules Monographs since the Standard solution includes the USP Anhydrotetracycline Hydrochloride RS. The USP Certificate has been updated to include this content and is now available in USP's Store (<https://store.usp.org>). The assigned value of Lot R11400 has already been corrected for the content of all impurities, including anhydrotetracycline hydrochloride. The provided anhydrotetracycline hydrochloride content only needs to be considered when USP 4-Epianhydrotetracycline Hydrochloride RS and USP Anhydrotetracycline Hydrochloride RS are included in the same solution. Lot R11400 remains suitable for its USP compendial uses.

USP posted a Notice of Intent to Revise (<https://www.uspnf.com/notices/tetracyclines-nitr-20201218>) for the USP Tetracycline, Tetracycline Hydrochloride and Tetracycline Hydrochloride Capsules Monographs on December 18, 2020 that proposes the following revision:

- Revise the Standard solution in the *Organic Impurities* by separating the impurity Reference Standards (RSs) to different Standard solutions for proper quantification of impurities
- This revision is proposed for the Tetracycline, Tetracycline Hydrochloride and Tetracycline Hydrochloride Capsules Monographs

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in Pharmacopeial Forum 47(4) [Jul.–Aug. 2021] pursuant to the Rules and Procedures. The comment period for this revision ends on September 30, 2021. In the absence of any adverse comments the proposed IRA will become official on Jan 1, 2022.

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

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