Tetracycline, Tetracycline Hydrochloride and Tetracycline Hydrochloride Capsules

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Expert Committee: Small Molecules 1

In accordance with the Rules and Procedures of the Council of Experts, this is to provide notice that the USP Small Molecules 1 Expert Committee intends to revise the Tetracycline, Tetracycline Hydrochloride and Tetracycline Hydrochloride Capsules monographs.

Comments were received indicating that USP Epitetracycline Hydrochloride RS contains a small amount of tetracycline hydrochloride and USP 4-Epianhydrotetracycline Hydrochloride RS used in the Standard solution contains a small amount of anhydrotetracycline. This affects the results obtained for 2-acetyl analog, anhydrotetracycline, and any individual unspecified impurity in the Tetracycline, Tetracycline Hydrochloride and Tetracycline Hydrochloride Capsules monographs, except for 2-acetyl analog impurity which is not controlled in the Tetracycline Hydrochloride Capsules monograph. The Expert Committee proposes to revise the Standard solution in the *Organic Impurities* sections of these monographs by separating the impurity Reference Standards (RSs) to different Standard solutions for proper quantification of impurities.

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 January 1, 2022.

Should you have any questions, please contact Praveen K. Pabba, Scientific Liaison (PKP@usp.org).