Trihexyphenidyl Hydrochloride Oral Solution and Trihexyphenidyl Hydrochloride Extended-Release Capsules

Type of Posting: Notice of Intent to Revise

Posting Date: 04–May–2016

Targeted Official Date: To be Determined

Expert Committee: Chemical Medicines Monographs 4

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 4 Expert Committee intends to revise Trihexyphenidyl Hydrochloride Oral Solution and Trihexyphenidyl Hydrochloride Extended-Release Capsules monographs to correct an error that was introduced when the *Assay* for the Trihexyphenidyl Hydrochloride monograph was modernized.

When the Trihexyphenidyl Hydrochloride monograph became official on May 1, 2016 in *USP 39–NF 34*, the cross-reference to the *Mobile phase* and *Chromatographic System* in the Trihexyphenidyl Hydrochloride Oral Solution, and Trihexyphenidyl Hydrochloride Extended-Release Capsules monographs to the *Assay* test in Trihexyphenidyl Hydrochloride monograph was broken, because the new assay test was not validated for use with the drug product.

The Assay in both monographs will be corrected so that the reference, "*Mobile phase* and *Chromatographic system*—Prepare as directed in the *Assay* under *Trihexyphenidyl Hydrochloride*" in the Oral Solution and Extended-Release Capsules monographs will be replaced with the Mobile phase and Chromatographic system conditions listed in the revision of *Trihexyphenidyl Hydrochloride* published in *USP 38–NF 33*---.

The process and timing for the revision will be determined following additional considerations by the Expert Committee and USP staff.

Should you have any questions, please contact Sridevi Ramachandran, Scientific Liaison to the Chemical Medicines Monographs 4 Expert Committee (SDR@usp.org).