Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets

Type of Posting: Notice of Intent to Revise
Posting Date: 20–Jul–2018
Targeted Official Date: 01–Aug–2018, Revision Bulletin
Expert Committee: Chemical Medicines Monographs 6

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 6 Expert Committee intends to revise the Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets monograph.

The Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets monograph was recently revised to add *Dissolution Test 7* via a Revision Bulletin that was published on June 29, 2018 and became official on July 1, 2018. Two transcription errors were subsequently discovered in this Revision Bulletin under the *Times* subsection for Pseudoephedrine Hydrochloride and *Standard stock solution A*. The *Times* subsection for Pseudoephedrine Hydrochloride should be “45 min, 3, 5, and 12 h” as shown in *Table 8*. In addition, the amount of methanol in the *Standard stock solution A* should be NMT 5% rather than NMT 0.5%.

It is anticipated that a Revision Bulletin will be published on July 27, 2018 and become official on August 1, 2018, which will contain revisions to *Dissolution Test 7*, pursuant to section 7.02 of the Rules and Procedures.
Should you have any questions, please contact Richard Nguyen, Associate Scientific Liaison (301–816–8170 or rbn@usp.org) or Tsion Bililign, Scientific Liaison (301-816-8286 or tb@usp.org).

CN-18-002-00