
[Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-Release Tablets](#)

Type of Posting: Notice of Intent to Revise

Posting Date: 01–Jun–2018; revised 04–Jun–2018*

Targeted Official Date: Revision Bulletin, 01–Mar–2019

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 Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-Release Tablets monograph.

Comments with supporting data were received that indicate the need to revise the limits from NMT 0.15% to NMT 0.2% for both naproxen sodium related unspecified impurity and pseudoephedrine hydrochloride related unspecified impurity in the Organic Impurities section to be consistent with FDA approved acceptance criteria.

It is anticipated that the revision will be published as a Revision Bulletin pursuant to section 7.02 of the Rules and Procedures. If approved by the Expert Committee, the Revision Bulletin will be posted on February 22, 2019 and becomes official on March 1, 2019. It is intended that this Revision Bulletin will supersede the Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-Release Tablets monograph which is being published in the *Second Supplement* to *USP 41–NF 36*, which also becomes official on March 1, 2019.

Should you have any questions, please contact Richard Nguyen, Associate Scientific Liaison (301–816–8170 or rhn@usp.org) or Tsion Billig, Scientific Liaison (301-816-8286 or tb@usp.org).

* This notice was revised on June 4, 2018 to revise the proposed Revision Bulletin publication date to align with the revised official date for *Second Supplement to USP 41–NF 36*.

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