Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-Release Tablets

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In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 2 Expert Committee has revised the Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Test 3* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). This revision also necessitates a change in the table numbering. Existing references to reagents and reagent names have been updated for consistency with official reagent entry names.

- *Dissolution Test 3* was validated using the Zorbax SB Phenyl brand of column with L11 packing. The typical retention time for naproxen (detected at 257 nm) is about 7 min. The typical retention time for pseudoephedrine (detected at 215 nm) is about 5.7 min.

The Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).