Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets

Type of Posting	Revision Bulletin
Posting Date	25-Apr-2025
Official Date	1-May-2025
Expert Committee	Small Molecules 5

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 5 Expert Committee has revised the Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Test 10* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). The revision also necessitates a change in the table numbering in the test for *Organic Impurities*.

- *Dissolution Test 10* was validated using the Partisil ODS-1 brand of column with L1 packing. The typical retention times for pseudoephedrine and fexofenadine are about 1.5 and 4 min, respectively.

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

Should you have any questions, please contact V. Durga Prasad, Senior Scientist II (91-40-4448-8723 or durgaprasad.v@usp.org).