

## **Metformin Hydrochloride Extended-Release Tablets**

Type of PostingRevision BulletinPosting Date26-Jan-2024Official Date1-Feb-2024

**Expert Committee** Small Molecules 3

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Metformin Hydrochloride Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Tests 27, 28,* and 29 to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s).

• Dissolution Test 27 was validated using the Phenomenex Luna C18 (2) brand of column with L1 packing. The typical retention time for metformin is about 4.5 min.

The Metformin 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 <a href="mailto:durgaprasad.v@usp.org">durgaprasad.v@usp.org</a>).