Metoprolol Succinate Extended-Release Tablets

Type of Posting	Revision Bulletin
Posting Date	30-Aug-2024
Official Date	1-Sep-2024
Expert Committee	Small Molecules 2

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 2 Expert Committee has revised the Metoprolol Succinate Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Tests 10, 11, 12,* and *13* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). Also, *Dissolution Test 8* is being restored to the text after it was inadvertently not included in a previous version of the text. Additionally, minor editorial changes have been made to update the monograph to current *USP* style. The revision also necessitates a change in the table numbering in the test for *Organic Impurities.*

- *Dissolution Test 8* was validated using the Welch Ultimate XB-C8 brand of column with L7 packing. The typical retention time for metoprolol is about 2.6 min.
- *Dissolution Test 10* was validated using the Hypersil BDS C8 brand of column with L7 packing. The typical retention time for metoprolol is about 2.3 min.
- *Dissolution Test 11* was validated using the ACE 5 C8 MAC-MOD brand of column with L7 packing. The typical retention time for metoprolol is about 1.9 min.
- *Dissolution Test 12* was validated using the Inertsil C8-3 brand of column with L7 packing. The typical retention time for metoprolol is about 3.8 min.
- *Dissolution Test 13* was validated using the Waters Xterra RP8 brand of column with L7 packing. The typical retention time for metoprolol is about 2.9 min.

The Metoprolol Succinate Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Brice Wagner, Scientist III (301-998-6832 or brice.wagner@usp.org).