Oseltamivir Phosphate Capsules

Type of Posting  Revision Bulletin
Posting Date  25-Mar-2022
Official Date  1-Apr-2022
Expert Committee  Small Molecules 1

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 1 Expert Committee has revised the Oseltamivir Phosphate Capsules monograph. The purpose of this revision is to add Dissolution Test 2 to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test. Labeling information has been incorporated to support the inclusion of Dissolution Test 2.

- Dissolution Test 2 was validated using the Symmetry C18 brand of column with L1 packing. The typical retention time for oseltamivir is about 6.1 min.

The Oseltamivir Phosphate Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Robyn Fales, Scientist IV (240-221-2047 or rnp@usp.org).