

Fluoxetine Capsules

Type of PostingRevision BulletinPosting Date24-Feb-2023Official Date1-Mar-2023

Expert Committee Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised the Fluoxetine 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 Zorbax StableBond-CN brand of column with L10 packing. The typical retention time for fluoxetine is about 3 min.

The Fluoxetine Capsules Revision Bulletin supersedes the currently official monograph.

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