Divalproex Sodium Extended-Release Tablets

Type of Posting                                      Revision Bulletin
Posting Date                                         16-Mar-2022
Official Date                                        17-Mar-2022
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 Divalproex Sodium Extended-Release Tablets monograph. The purpose of the revision is to add Dissolution Test 12 to accommodate FDA-approved drug products with different dissolution conditions and tolerances than the existing dissolution test(s).

- Dissolution Test 12 was validated using the NovaPak Phenyl brand of column with L11 packing. The typical retention time for valproic acid is about 5.5 min.

The Divalproex Sodium Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

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