

Divalproex Sodium Delayed-Release Capsules

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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 Delayed-Release Capsules monograph. The purpose of this revision is to add *Dissolution Test* 6 to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s).

• Dissolution Test 6 was validated using the NovaPak Phenyl brand of column with L11 packing. The typical retention time for valproic acid is about 6.0 min.

The Divalproex Sodium Delayed-Release Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Mark Tiedje, Senior Scientist II (301-816-8535 or mark.tiedje@usp.org).