Divalproex Sodium Delayed-Release Capsules

Posting Date: 23 November 2011

Official Date: 01 December 2011

Expert Committee: Monographs - Small Molecules 4

Reason for Revision: Compliance

In accordance with the Rules and Procedures of the 2010-2015 Council of Experts, the Monographs - Small Molecules 4 Expert Committee has revised the palproex Sodium Delayed-Release Capsules monograph. The purpose for the revision is to add Dissolution Test 3 for a product approved by the FDA. The new test was validated using a Waters Nova Pak Phenyl brand of L11 column. The typical retention time for palproex sodium is about 2.9 min.

The palproex Sodium Delayed-Release Capsules Revision Bulletin supersedes the currently official monograph and replaces the monograph in the Revision Bulletin posted on 29 July 2011 which became official 01 August 2011. This Revision Bulletin will be incorporated in the Second Supplement to *USP 35–NF 30*.

Should you have any questions, please contact R. Ravichandran (301-816-8330, rr@usp.org) or H. Joyce. (301-881-0666 x8442, hrj@usp.org).