Rufinamide Tablets

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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 Rufinamide Tablets monograph. The purpose of the revision is to add *Dissolution Test 3* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). Labeling Information has been incorporated to support the inclusion of *Dissolution Test 3*.

- *Dissolution Test 3* was validated using the Waters Xterra RP18 brand of column with L1 packing (4.6-mm × 15-cm, 5-µm). The sponsor also lists the use of an ACE column. The typical retention time for rufinamide is about 3.3 min.

The Rufinamide Tablets Revision Bulletin supersedes the currently official monograph.

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