

Rufinamide Tablets

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Expert Committee

Revision Bulletin

15-Sep-2022

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 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(s).

• Dissolution Test 2 was validated using an Inertsil ODS-3V brand of column with L1 packing. The typical retention time for rufinamide is about 3.1 min.

The Rufinamide Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Claire Chisolm, Senior Scientist II (301-230-3215 or cnc@usp.org).