Tacrolimus Capsules

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Expert Committee	Small Molecules 1

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 1 Expert Committee has revised the Tacrolimus Capsules monograph. The purpose of this revision is to add *Dissolution Test 8* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). The revision also necessitates a change in the table numbering in the *Organic Impurities* tests.

- *Dissolution Test 8* was validated using the Hypurity C18 brand of column with L1 packing. The typical retention time for tacrolimus is about 11 min.

The Tacrolimus Capsules Revision Bulletin supersedes the currently official monograph.

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