Levothyroxine Sodium Tablets

Type of Posting	Revision Bulletin
Posting Date	27-May-2022
Official Date	1-Jun-2022
Expert Committee	Small Molecules 3

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Levothyroxine Sodium Tablets monograph. The purpose of this revision is to add *Dissolution Test 7* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution tests. The test was previously published as a Pending Notice of Intent to Revise (NITR) in April 2020, but the final approved times and/or tolerances are different than those published in the NITR.

- *Dissolution Test 7* was validated using the Nucleosil 100-10 C18 brand of column with L1 packing (4.6-mm x 250 cm, 10-µm). The typical retention time for levothyroxine is about 10 min.

The Levothyroxine Sodium 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).