



Methylphenidate Hydrochloride Extended-Release 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 Methylphenidate Hydrochloride Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Tests 13, 14, and 15* 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 test for *Organic Impurities*.

- *Dissolution Test 13* was validated using the Inertsil ODS-3 brand of column with L1 packing. The typical retention time for methylphenidate is about 3.0 min.
- *Dissolution Test 14* was validated using the Symmetry C8 brand of column with L7 packing. The typical retention time methylphenidate is about 2.4–3.2 min.
- *Dissolution Test 15* was validated using the Inertsil ODS-3 brand of column with L1 packing. The typical retention time for methylphenidate is about 3.0 min.

The Methylphenidate Hydrochloride Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Jasmine Lawrence, Scientist IV (301-230-6363 or jasmine.lawrence@usp.org).