



Mesalamine Extended-Release Capsules

Type of Posting	Revision Bulletin
Posting Date	28-Jun-2024
Official Date	1-Jul-2024
Expert Committee	Small Molecules 2

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 2 Expert Committee has revised the Mesalamine Extended-Release Capsules monograph. The purpose of this revision is to add *Dissolution Test 6* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). On the basis of comments received, sample preparation in the *Assay* and in the test for *Organic Impurities* has been revised to provide flexibility. This revision also necessitates a change in the table numbering in the test for *Organic Impurities*.

- *Dissolution Test 6* was validated using the Inertsil ODS 3V brand of column with L1 packing. The typical retention time for mesalamine is about 4 min.

The Mesalamine Extended-Release Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).