

Mesalamine Extended-Release Capsules

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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 5* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). This revision also necessitates a change in the table numbering.

• *Dissolution Test 5* was validated using the Hypersil BDS C18 brand of column with L1 packing. The typical retention time for mesalamine is about 3.5 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).