

Mexiletine Hydrochloride 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 Mexiletine Hydrochloride Capsules monograph. The purpose of this revision is to add *Dissolution Test 2* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test. Labeling information has been incorporated to support the inclusion of *Dissolution Test 2*.

- *Dissolution Test 2* was validated using the μ Bondapak C18 brand of column with L1 packing. The typical retention time for mexiletine is about 5 min.

Additionally, minor editorial changes have been made to update the monograph to current *USP* style.

The Mexiletine Hydrochloride Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Robyn Fales, Senior Scientist I (240-221-2047 or rnp@usp.org).