## Topiramate Extended-Release Capsules

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In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised the Topiramate Extended-Release 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(s). The revision also necessitates a change in the table numbering in the tests for *Limit of Sulfamate and Sulfate* and *Organic Impurities*. *Labeling* information has been incorporated to support the inclusion of *Dissolution Test 2*.

- *Dissolution Test 2* was validated using the Synergi Max-RP brand of column with L87 packing. The typical retention time for topiramate is about 5 min.

Existing references to reagents and reagent names also have been updated for consistency with official reagent entry names.

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

Should you have any questions, please contact V. Durga Prasad, Senior Scientist II (91-40-4448-8723 or durgaprasad.v@usp.org).