Diclofenac Sodium and Misoprostol Delayed-Release Tablets

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In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Diclofenac Sodium and Misoprostol Delayed-Release Tablets 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. Filter information under *Identification A* has been updated to allow additional flexibility as it may be obtained from different vendors. *Labeling* information has been incorporated to support the inclusion of *Dissolution Test 2*.

- *Dissolution Test 2* was validated using the Zorbax SB-Phenyl brand of column with L11 packing. The typical retention time for misoprostol is about 8 min.

The Diclofenac Sodium and Misoprostol Delayed-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Brice Wagner, Scientist III, (301 998-6832 or brice.wagner@usp.org).