Isosorbide Dinitrate Tablets

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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 Isosorbide Dinitrate Tablets monograph. The purpose of this revision is to add *Dissolution Test 2* and *Dissolution Test 3* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). *Labeling* information has been incorporated to support the inclusion of *Dissolution Test 2* and *Dissolution Test 3*.

- *Dissolution Test 2* was validated using the SUPELCOSIL LC-18 brand of column with L1 packing. The typical retention time for isosorbide dinitrate is about 2.2 min.

- *Dissolution Test 3* was validated using the Xterra-RP 18 brand of column with L1 packing. The typical retention time for isosorbide dinitrate is about 4.5 min.

The Isosorbide Dinitrate Tablets 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).