

Nifedipine Extended-Release 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 Nifedipine Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Test 16* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s).

• Dissolution Test 16 was validated using the Luna C18(2) brand of L1 column. The typical retention time for nifedipine is about 5.5 min.

Existing references to reagents also have been updated for consistency with the reagent entry names. For additional information about reagent cross-references, please see the related Compendial Notice.

The Nifedipine Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Devendra Pratap Singh, Associate Scientific Liaison (404-448-8975 or dxp@usp.org).