



## Nifedipine Extended-Release Tablets

<b>Type of Posting</b>	Revision Bulletin
<b>Posting Date</b>	30-Aug-2024
<b>Official Date</b>	1-Sep-2024
<b>Expert Committee</b>	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 Tests 17* and *18* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s).

- *Dissolution Test 17* was validated using the Zorbax Eclipse XDB C18 brand of 4.6-mm × 150-mm column with 5- $\mu$ m L1 packing. The typical retention time for nifedipine is about 6.6 min.
- *Dissolution Test 18* was validated using the Phenomenex Gemini 110A° C-18 brand of 4.6-mm × 250-mm column with 5- $\mu$ m L1 packing. The typical retention time for nifedipine is about 2.5–4.5 min.

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

Should you have any questions, please contact Jasmine McFarland, Scientist III (301-230-6363 or [jasmine.mcfarland@usp.org](mailto:jasmine.mcfarland@usp.org)).