

Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Aug-2022
 Document Type: USP Monographs
 DocId: GUID-B32857A0-C588-4197-BA7C-3615D43E5759_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M32660_04_01
 DOI Ref: s0yv1

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Felodipine Extended-Release Tablets

DEFINITION

Felodipine Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of felodipine ($C_{18}H_{19}Cl_2NO_4$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer solution: 6.9 mg/mL of [monobasic sodium phosphate](#) in [water](#). Adjust with 1 M [phosphoric acid](#) to a pH of 3.0 ± 0.05 .

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer solution* (40:20:40)

Standard stock solution: 2 mg/mL of [USP Felodipine RS](#) in [methanol](#). Sonication may be necessary for complete dissolution.

Standard solution: 0.02 mg/mL of [USP Felodipine RS](#) from the *Standard stock solution* in *Mobile phase*

Sample stock solution: Nominally 0.1 mg/mL of felodipine prepared as follows. Dissolve a quantity equivalent to 10 mg of felodipine from powdered Tablets (NLT 10) in 40 mL of [acetonitrile](#) and 20 mL of [methanol](#) in a 100-mL volumetric flask, and sonicate for 5 min. Add about 30 mL of *Buffer solution*, and shake by mechanical means for 30 min. Allow the solution to cool to room temperature, and dilute with *Buffer solution* to volume. Centrifuge a portion of the solution at high speed for 15 min.

Sample solution: Nominally 0.02 mg/mL of felodipine prepared as follows. Transfer 10 mL of the supernatant from the *Sample stock solution* to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume. Pass a portion of this solution through a filter of 0.5- μ m or finer pore size, discarding the first 4 mL of the filtrate.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 362 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

Column: 4.6-mm $\times$ 15-cm; 4- μ m packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 40 μ L

Run time: NLT 2 times the retention time of felodipine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of felodipine ($C_{18}H_{19}Cl_2NO_4$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of felodipine from the *Sample solution*

r_S = peak response of felodipine from the *Standard solution*

C_S = concentration of [USP Felodipine RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of felodipine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: pH 6.5 phosphate buffer with 1% [sodium lauryl sulfate](#) (Transfer 206 mL of 1 M [monobasic sodium phosphate](#), [▲](USP 1-Aug-2022) 196 mL of 0.5 M [dibasic sodium phosphate anhydrous](#), and 50.0 g of [sodium lauryl sulfate](#) to a 5000-mL volumetric flask. Add about 4000 mL of [water](#), and mix well. If necessary, adjust with 1 N [sodium hydroxide](#) to a pH of 6.5. Dilute with [water](#) to volume); 500 mL

Apparatus 2: 50 rpm, [▲]with stationary basket. See [\(711\)](#), [Figures 2b](#) and [2c](#). [▲](USP 1-Aug-2022)

Times: 2, 6, and 10 h

Buffer solution: [▲]Prepare as directed for Assay. [▲](USP 1-Aug-2022)

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer solution* (25:10:20)

Standard stock solution: 0.25 mg/mL of [USP Felodipine RS](#) in [alcohol](#)

Standard solution: (0.6 L/500) mg/mL of [USP Felodipine RS](#) from the *Standard stock solution* in *Medium*, where L is the label claim in mg/Tablet

Sample solution: [▲][▲](USP 1-Aug-2022) Pass a 10-mL portion of the solution under test, obtained at each time interval, through a suitable filter.

[▲][▲](USP 1-Aug-2022)

Chromatographic system: Proceed as directed in the Assay, except for the *Injection volume*.

Injection volume: 100 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of felodipine ($C_{18}H_{19}Cl_2NO_4$) in the sample withdrawn from the vessel at each time point (i):

$$\text{Result}_i = (r_U/r_S) \times C_S$$

r_U = peak response of felodipine from the *Sample solution* at each time point, i

r_S = peak response of felodipine from the *Standard solution*

C_S = concentration of [USP Felodipine RS](#) in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of felodipine ($C_{18}H_{19}Cl_2NO_4$) dissolved at each time point (i):

$$\text{Result}_1 = C_i \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_S)] + (C_1 \times V_S)\} \times (1/L) \times 100$$

$$\text{Result}_3 = \{[C_3 \times [V - (2 \times V_S)]] + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

C_i = concentration of felodipine in the *Sample solution* at the specified time point (mg/mL)

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

V_S = volume of the *Sample solution* withdrawn at each time point, i (mL)

Tolerances: See [Table 1](#).

Table 1

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	10–30
2	6	42–68
3	10	NLT 75

The percentages of the labeled amount of felodipine ($C_{18}H_{19}Cl_2NO_4$) dissolved at the times specified conform to [Dissolution \(711\)](#), [Acceptance Table 2](#).

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 1% (w/v) [polysorbate 80](#) [▲]in [water](#) [▲](USP 1-Aug-2022); 500 mL

Apparatus 1: 100 rpm

Times: 1, 4, and 8 h