Nifedipine Extended-Release Tablets

DEFINITION

Nifedipine Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$). [NOTE—Nifedipine, when exposed to daylight and certain wavelengths of artificial light, readily converts to a nitrosophenylpyridine derivative. Exposure to UV light leads to the formation of a nitrophenylpyridine derivative. Perform assays and tests in the dark or under golden fluorescent or other low-actinic light. Use low-actinic glassware.]

IDENTIFICATION

- **A.** The retention time of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B. ULTRAVIOLET ABSORPTION ⟨197U⟩**
  Standard stock solution: Prepare as directed in the *Assay*.
  Standard solution: 0.02 mg/mL in *Mobile phase* from the *Standard stock solution*
  Sample stock solution: Prepare as directed in the *Assay*.
  Sample solution: 0.02 mg/mL in *Mobile phase* from the *Sample stock solution*

ASSAY

- **PROCEDURE**
  [NOTE—Conduct the *Assay* promptly after preparation of the *Standard solution* and the *Sample solution*.]
  Mobile phase: Acetonitrile, methanol, and water (25:25:50)
  Standard stock solution: 1 mg/mL of USP Nifedipine RS in methanol
  Standard solution: 0.1 mg/mL of USP Nifedipine RS from the *Standard stock solution* in *Mobile phase*
  Sample stock solution: Dissolve an amount equivalent to 420 mg of nifedipine from powdered Tablets in 130 mL of water in a 250-mL volumetric flask; or transfer the intact Tablets to a 400-mL, high-speed blender cup containing 130 mL of water. Homogenize until a uniform suspension is achieved (about 2 min), and transfer the suspension with the aid of a mixture of acetonitrile and methanol (1:1) to a 250-mL volumetric flask. Dilute with a mixture of acetonitrile and methanol (1:1) to volume, and stir for 30 min. Centrifuge the resulting suspension to obtain a clear supernatant.
  Sample solution: 0.1 mg/mL of nifedipine prepared as follows. Transfer 3.0 mL of the *Sample stock solution* to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and filter. [NOTE—Reserve a portion of this solution for use as the *Sample solution* in the test for *Organic Impurities*.]
  Chromatographic system
  (See *Chromatography ⟨621⟩, System Suitability*.)
  Mode: LC
  Detector: UV 265 nm
  Column: 4.6-mm × 25-cm; 5-μm packing L1
  Guard column: 2.1-mm × 3-cm; packing L1
  Flow rate: 1 mL/min
  Injection size: 25 μL
  System suitability
  Sample: *Standard solution*
  Suitability requirements
  Column efficiency: NLT 4000 theoretical plates
  Tailing factor: NMT 1.5
  Relative standard deviation: NMT 1.0%
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Calculate the percentage of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of USP Nifedipine RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of nifedipine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **DISSOLUTION ⟨711⟩**
  Test 1: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.
  Medium: Water; 50 mL
  Apparatus 7 (See *Drug Release ⟨724⟩*): 15–30 cycles/min. Do not use the reciprocating disk; use a 25-cm plexiglas rod, the perimeter of the Tablets being affixed to the rod with a water-insoluble glue. The solution containers are 25-mm test tubes, 150–200 mm in length, and the water bath is maintained at 37 ± 0.5°. At the end of each specified test interval, the systems are transferred to the next row of new test tubes containing 50 mL of fresh *Medium*.
  Times: 4, 8, 12, 16, 20, and 24 h
  Diluent: A mixture of methanol and water (1:1)
  Standard solution: Transfer 50 mg of USP Nifedipine RS to a 100-mL volumetric flask. Dissolve in 50 mL of methanol, and dilute with water to volume. Quantitatively dilute this solution with *Diluent* to obtain solutions having suitable known concentrations.
  Sample solution: Use portions of the solution under test, passed through a suitable filter of 0.4-μm pore size, suitably diluted with methanol, and stepwise if necessary, with *Diluent* to obtain a final mixture consisting of equal parts of methanol and water.
  Instrumental conditions
    Mode: UV
    Analytical wavelength: 338 nm
    Cell: 0.5 cm
  Analysis: Determine the amount of nifedipine ($C_{17}H_{18}N_2O_6$) released in the *Sample solution* at each 4-h interval from UV absorbances. [NOTE—For the 4-h time period, determine the absorbance at 456 nm, and use this determination to correct for excipient interference.]
  Tolerances: See *Table 1*.

Table 1

Time (h)	Amount Dissolved[a]
4	5%–17%
8	—
12	43%–80%
16	—
20	—
24	NLT 80%

[a] The amount dissolved is expressed in terms of the labeled Tablet strength rather than in terms of the labeled total contents.

The cumulative percentages of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$), released at the times specified, conform to *Acceptance Table 2* in *Dissolution ⟨711⟩*.
Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Solution A: Dissolve 330.9 mg of sodium phosphate and 38 g of citric acid in water in a 1-L volumetric flask. Add 10 mL of phosphoric acid, and dilute with water to volume.

Medium: Mix 125.0 mL of *Solution A* and 1 L of 10% sodium lauryl sulfate solution, and dilute to 10 L. Adjust, if necessary, to a pH of 6.8; 900 mL.

Apparatus 2: 50 rpm, with sinkers (see *Figure 2a*) in *Dissolution* ⟨711⟩

Times: 3, 6, and 12 h

Mobile phase: Acetonitrile and water (7:3)

Standard stock solution: 1.11 mg/mL of USP Nifedipine RS in methanol

Standard solution: 0.1 mg/mL of USP Nifedipine RS from the *Standard stock solution* in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
  Mode: LC
  Detector: UV 350 nm
  Column: 4.0-mm × 125-mm; 3-µm packing L1
  Temperature: 40°
  Flow rate: 1.5 mL/min
  Injection size: 20 µL

System suitability
  Sample: *Standard solution*
  Suitability requirements
    Column efficiency: NLT 2000 theoretical plates
    Tailing factor: NMT 1.5
    Relative standard deviation: NMT 2.0%

Analysis
  Samples: *Standard solution* and *Sample solution*
  Determine the amount of nifedipine ($C_{17}H_{18}N_2O_6$) dissolved.

Tolerances: See *Table 2*.

Table 2

Time (h)	Amount Dissolved
3	10%–30%
6	40%–65%
12	NLT 80%

The percentages of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$), released in vivo and dissolved at the times specified, conform to *Acceptance Table 2* in *Dissolution* ⟨711⟩.

Tolerances:

Test 3: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

For Tablets labeled to contain 30 mg of nifedipine: Phase 1

  Medium: 0.05 M phosphate buffer, pH 7.5; 900 mL
  Apparatus 2: 100 rpm
  Time: 1 h
  Standard solution: 0.034 mg/mL of USP Nifedipine RS in *Medium*. [NOTE—If necessary, a volume of methanol, not exceeding 10% of the final volume, can be used to help solubilize nifedipine.]
  Sample solution: Pass a portion of the solution under test through a suitable filter.
  Instrumental conditions
    Mode: UV
    Analytical wavelength: 238 nm
    Cell: 0.5 cm
  Analysis: [NOTE—After the run, take the Tablet out of the dissolution vessel, adapt a sinker to it, and transfer the

Tablet with the sinker to the dissolution vessel containing the *Medium* for *Phase 2*.] Determine the amount of nifedipine ($C_{17}H_{18}N_2O_6$) released in *Phase 1*, using filtered portions of the *Sample solution*, in comparison with the *Standard solution*, using the *Medium* as the blank.

For Tablets labeled to contain 30 mg of nifedipine: Phase 2

  Medium: 0.5% sodium lauryl sulfate in simulated gastric fluid without enzyme, pH 1.2; 900 mL
  Apparatus 2: 100 rpm
  Times: 1, 4, 8, and 12 h
  Standard solution: 0.034 mg/mL of USP Nifedipine RS in *Medium*. [NOTE—If necessary, a volume of methanol, not exceeding 10% of the final volume, can be used to help solubilize nifedipine.]
  Sample solution: Pass a portion of the solution under test through a suitable filter.
  Instrumental conditions
    Mode: UV
    Analytical wavelength: 238 nm
  Analysis: Determine the amount of nifedipine ($C_{17}H_{18}N_2O_6$) released in *Phase 2*, using filtered portions of the *Sample solution*, in comparison with the *Standard solution*, using *Medium* as the blank.
  Tolerances: See *Table 3*.

Table 3

Time (h)	Amount Dissolved[a]
1	NMT 30%
4	30%–55%
8	NLT 60%
12	NLT 80%

[a] For each dosage unit, add the amount dissolved in phosphate buffer, pH 7.5 from *Phase 1* to the amount dissolved at each time point in *Phase 2*.

The cumulative percentages of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$), released in vivo and dissolved at the times specified, conform to *Acceptance Table 2* in *Dissolution* ⟨711⟩.

For Tablets labeled to contain 60 mg of nifedipine: Phase 1

  Medium: 0.05 M phosphate buffer, pH 7.5; 900 mL
  Sample solution: Pass a portion of the solution under test through a suitable filter.
  Instrumental conditions
    Mode: UV
    Analytical wavelength: 238 nm
  Analysis: [NOTE—After the run, take the Tablet out of the dissolution vessel, adapt a sinker to it, and transfer the Tablet with the sinker to the dissolution vessel containing the *Medium* for *Phase 2*.] Determine the amount of nifedipine ($C_{17}H_{18}N_2O_6$) released in *Phase 1*, using filtered portions of the *Sample solution*, in comparison with the *Standard solution*, using the *Medium* as the blank.
  Apparatus 2: 100 rpm
  Time: 25 min
  Standard solution: 0.067 mg/mL of USP Nifedipine RS in *Medium*. [NOTE—If necessary, a volume of methanol, not exceeding 10% of the final volume, can be used to help solubilize nifedipine.]

For Tablets labeled to contain 60 mg of nifedipine: Phase 2

  Medium: 0.5% sodium lauryl sulfate in simulated gastric fluid without enzyme, pH 1.2; 900 mL

Apparatus 2: 100 rpm
Times: 1, 4, 8, and 12 h
Standard solution: 0.067 mg/mL of USP Nifedipine RS in *Medium*. [NOTE—If necessary, a volume of methanol, not exceeding 10% of the final volume, can be used to help solubilize nifedipine.]
Sample solution: Pass a portion of the solution under test through a suitable filter.
Instrumental conditions
  Mode: UV
  Analytical wavelength: 238 nm
Analysis: Determine the amount of nifedipine ($C_{17}H_{18}N_2O_6$) released in *Phase 2*, using filtered portions of the *Sample solution*, in comparison with the *Standard solution*, using *Medium* as the blank.
Tolerances: See *Table 4*.

Table 4

Time (h)	Amount Dissolved[a]
1	NMT 30%
4	40%–70%
8	NLT 70%
12	NLT 80%

[a] For each dosage unit, add the amount dissolved in phosphate buffer, pH 7.5 from *Phase 1* to the amount dissolved at each time point in *Phase 2*.

The cumulative percentages of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$), released in vivo and dissolved at the times specified, conform to *Acceptance Table 2* in *Dissolution* ⟨711⟩.

Test 4: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 4*.
Medium: 0.5% sodium lauryl sulfate in simulated gastric fluid without enzyme, pH 1.2; 900 mL
Apparatus 2: 100 rpm
Times: 1, 4, and 12 h
Standard solution: 0.067 mg/mL of USP Nifedipine RS for Tablets labeled to contain 60 mg, and 0.034 mg/mL of USP Nifedipine RS for Tablets labeled to contain 30 mg, in *Medium*. [NOTE—If necessary, a volume of methanol, not exceeding 10% of the final volume, can be used to help solubilize nifedipine.]
Sample solution: Pass a portion of the solution under test through a suitable filter.
Instrumental conditions
  Mode: UV
  Analytical wavelength: UV 238 nm
  Cell: 0.5 cm
Analysis: Determine the amount of nifedipine ($C_{17}H_{18}N_2O_6$) released, using filtered portions of the *Sample solution*, in comparison with the *Standard solution*, using the *Medium* as the blank.
Tolerances: See *Table 5* and *Table 6*.

Table 5
For Tablets Labeled to Contain 30 mg of Nifedipine

Time (h)	Amount Dissolved
1	12%–35%
4	44%–67%
12	NLT 80%

Table 6
For Tablets Labeled to Contain 60 mg of Nifedipine

Time (h)	Amount Dissolved
1	10%–30%
4	40%–63%
12	NLT 80%

The cumulative percentages of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$), released at the times specified, conform to *Acceptance Table 2* in *Dissolution* ⟨711⟩.

Test 5: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 5*.
Medium: Water; 50 mL
Apparatus 7: (See *Drug Release* ⟨724⟩.) Use a 25-cm plexi-glas rod, the perimeter of the Tablets being affixed to the rod with a water-insoluble glue; 30 dips/min. The solution containers are 25-mm test tubes, 150–200 mm in length, and the water bath is maintained at $37 \pm 0.5°$.
Times: 4, 12, and 24 h
Diluent A: Methanol and acetonitrile (1:1)
Diluent B: *Diluent A* and water (1:1)
Standard stock solution: 50 mg of USP Nifedipine RS in *Diluent A* and water (50:50)
Standard solutions: 0.01, 0.05, and 0.20 mg/mL solutions, from the *Standard stock solution* in *Diluent B*, that are used at 4-, 12-, and 24-h sampling
Sample solution: Pass a portion of the solution under test through a suitable filter.
Instrumental conditions
  Mode: UV
  Analytical wavelength: 238 nm
  Cell: 0.5 cm
Analysis: [NOTE—For the 4-h time period, filter the solution under test, and determine the absorbance at 456 nm. Use this absorbance value to correct for excipient interference at the other time points.] Determine the amount of nifedipine released at each interval on portions of the *Sample solution* passed through a suitable 0.45-μm filter, suitably diluted, if necessary, with *Diluent A* and water to obtain a final mixture of water, methanol, and acetonitrile (2:1:1), in comparison with the appropriate *Standard solution*, using *Diluent B* as the blank.
Tolerances: See *Table 7*.

Table 7

Time (h)	Amount Dissolved
4	NMT 14%
12	39%–75%
24	NLT 75%

The cumulative percentages of the labeled amount of nifedipine, released in vivo and dissolved at the times specified, conform to *Acceptance Table 2* in *Dissolution* ⟨711⟩.

Test 6: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 6*.
Medium: Simulated gastric fluid without enzyme containing 0.5% of sodium lauryl sulfate, pH 1.2; 900 mL, deaerated
Apparatus 1: 100 rpm
Times: 1, 4, and 12 h
Standard stock solution: 0.33 mg/mL of USP Nifedipine RS in methanol

Standard solution: Quantitatively dilute the *Standard stock solution* with *Medium* to obtain a solution having a concentration of about 0.033 mg/mL.
Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.
Detector: UV 329 nm
Path length: 0.5 cm
Blank: *Medium*
Tolerances: See *Table 8.*

Table 8

Time (h)	Amount Dissolved
1	NMT 15%
4	20%–40%
12	NLT 80%

The cumulative percentages of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$) dissolved at the times specified conform to *Acceptance Table 2* in *Dissolution ⟨711⟩*.
•**Test 7:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 7.*
Medium: pH 1.2 simulated gastric fluid without enzyme containing 0.5% sodium lauryl sulfate; 900 mL
Apparatus 2: 100 rpm, with three-prong sinker
Times: 1, 4, and 12 h
Standard solution: (L/900) mg/mL of USP Nifedipine RS in *Medium*, where L is the label claim, in mg, of nifedipine. A small amount of methanol, not exceeding •6–7%• (RB 1-Oct-2010) of the final volume of the first dilution, can be used to solubilize nifedipine.
Sample solution: Pass a portion of the solution under test through a suitable filter.
Detector: UV 238 nm
Path length: 1 mm, flow cell
Blank: *Medium*
Tolerances: See *Table 9.*

Table 9

Time (h)	Amount Dissolved
1	NMT 15%
4	25%–50%
12	NLT 80%

The cumulative percentages of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$) dissolved at the times specified conform to *Acceptance Table 2* in *Dissolution ⟨711⟩*.•(RB 1-Aug-2010)
•**Test 8:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 8.*
Acid stage medium: pH 1.2 simulated gastric fluid without enzyme containing 3% polysorbate 80; 250 mL
Apparatus 3: 20 dpm, 20 mesh polypropylene screen on the bottom; 1 min drip time. The Tablet is automatically transferred by the apparatus to the next set of vessels for each time point.
Time: 1 h
Buffer stage medium: 0.01 M sodium phosphate buffer, pH 6.8 containing 3% polysorbate 80 (dissolve 8.3 g of monobasic sodium phosphate and 1 g of sodium hydroxide in 6 L of water, adjust with either diluted sodium hydroxide or phosphoric acid to a pH of 6.8 ± 0.05, and add 180 g of polysorbate 80); 250 mL

Times: 2, 8, 12, and 24 h
Mobile phase: Acetonitrile, methanol, and water (35:35:30)
Standard stock solution: 1 mg/mL of USP Nifedine RS in *Buffer stage medium*. A small amount of methanol, about 40% of the final volume, can be used to dissolve nifedipine.
Standard solution: (L/1000) mg/mL in *Buffer stage medium*, from the *Standard stock solution*, where L is the Tablet label claim in mg/Tablet
Sample solution: Pass a portion of the solution under test through a suitable filter.
Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability.*)
  Mode: LC
  Detector: UV 338 nm
  Column: 4.6-mm × 25-cm; packing L1
  Temperature: 30°
  Flow rate: 1.5 mL/min
  Injection size: 10 µL
System suitability
  Sample: *Standard solution*
  Suitability requirements
    Column efficiency: NLT 4000 theoretical plates
    Tailing factor: NMT 1.7
    Relative standard deviation: NMT 2.0%
Analysis: Calculate the percentage of the labeled amount of nifedipine dissolved at each time point.
At 1 h:

$$D_1 = (r_U/r_S) \times (C_S/L) \times V \times 100$$

At 2 h:

$$D = (r_U/r_S) \times (C_S/L) \times V \times 100$$

$$D_2 = D_1 + D$$

At 8 h:

$$D = (r_U/r_S) \times (C_S/L) \times V \times 100$$

$$D_8 = D_2 + D$$

At 12 h:

$$D = (r_U/r_S) \times (C_S/L) \times V \times 100$$

$$D_{12} = D_8 + D$$

At 24 h:

$$D = (r_U/r_S) \times (C_S/L) \times V \times 100$$

$$D_{24} = D_{12} + D$$

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of the *Standard solution* (mg/mL)
L = label claim (mg/Tablet)
V = volume of *Medium*, 250 mL
Tolerances
  Acid stage: NMT 5% of the labeled amount of nifedipine is dissolved in 1 h.

Buffer stage: See *Table 10.*

Table 10

Time (h)	Amount Dissolved
1	NMT 5%
2	0%–10%
8	25%–60%
12	45%–85%
24	NLT 80%

The cumulative percentages of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$) dissolved at the times specified conform to *Acceptance Table 2* in *Dissolution* ⟨711⟩.●(RB 1-Oct-2010)

• **UNIFORMITY OF DOSAGE UNITS** ⟨905⟩: Meet the requirements

IMPURITIES

• **ORGANIC IMPURITIES**

[NOTE—Conduct this test promptly after preparation of the *Standard nifedipine solution* and the *Sample solution.*]

Mobile phase: Acetonitrile, methanol, and water (25:25:50)

Quantitative limit stock solution A: 1 mg/mL of USP Nifedipine Nitrophenylpyridine Analog RS in methanol

Quantitative limit solution A: 6 µg/mL of USP Nifedipine Nitrophenylpyridine Analog RS from *Quantitative limit stock solution A* in *Mobile phase*

Quantitative limit stock solution B: 1 mg/mL of USP Nifedipine Nitrosophenylpyridine Analog RS in methanol

Quantitative limit solution B: 1.5 µg/mL of USP Nifedipine Nitrosophenylpyridine Analog RS from *Quantitative limit stock solution B* in *Mobile phase*

Standard nifedipine stock solution: 1 mg/mL of USP Nifedipine RS in methanol

Standard nifedipine solution: 0.3 mg/mL of USP Nifedipine RS from *Standard nifedipine stock solution* in *Mobile phase*

System suitability solution: *Standard nifedipine solution*, *Quantitative limit solution A*, and *Quantitative limit solution B* (1:1:1)

Standard solution: *Quantitative limit solution A*, *Quantitative limit solution B*, and *Mobile phase* (1:1:1). [NOTE—Each mL of this solution contains about 2 µg of USP Nifedipine Nitrophenylpyridine Analog RS and 0.5 µg of USP Nifedipine Nitrosophenylpyridine Analog RS.]

Sample solution: Use a portion of the *Sample solution* prepared as directed in the *Assay.*

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability.*)

Mode: LC

Detector: UV 265 nm

Column: 4.6-mm × 25-cm; packing L1

Guard column: 2.1-mm × 3-cm; packing L1

Flow rate: 1 mL/min

Injection size: 25 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 1.5 between the nitrophenylpyridine analog and nitrosophenylpyridine analog peaks; NLT 1.0 between the nitrosophenylpyridine analog and nifedipine peaks

Relative standard deviation: NMT 10% for each analog

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each analog in the portion of Tablets taken:

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

r_U = peak response of the corresponding analog from the *Sample solution*

r_S = peak response of the corresponding analog from the *Standard solution*

C_S = concentration of the appropriate analog USP Reference Standard in the *Standard solution* (µg/mL)

C_U = nominal concentration of nifedipine in the *Sample solution* (µg/mL)

Acceptance criteria: NMT 2.0% of nifedipine nitrophenylpyridine analog and NMT 0.5% of nifedipine nitrosophenylpyridine analog, both relative to the nifedipine content

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and store at controlled room temperature.

• **LABELING:** The labeling indicates the *Dissolution Test* with which the product complies.

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Nifedipine RS

USP Nifedipine Nitrophenylpyridine Analog RS
Dimethyl 4-(2-nitrophenyl)-2,6-dimethylpyridine-3,5-dicarboxylate
$C_{17}H_{16}N_2O_6$ 344.33

USP Nifedipine Nitrosophenylpyridine Analog RS
Dimethyl 4-(2-nitrosophenyl)-2,6-dimethylpyridine-3,5-dicarboxylate
$C_{17}H_{16}N_2O_5$ 328.33