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Nifedipine Capsules

DEFINITION

Nifedipine Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$).

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

Change to read:

• **A.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2019)

Change to read:

• **B.** The retention time of the ▲major peak of the▲ (USP 1-May-2019) *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure:** Protect ▲all solutions containing nifedipine▲ (USP 1-May-2019) from actinic light. 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 in *Mobile phase* from *Standard stock solution*

▲**Sample stock solution:** Nominally 1 mg/mL of nifedipine prepared as follows. Transfer the contents of NLT 5 Capsules to a suitable volumetric flask. Dilute with methanol to volume.▲ (USP 1-May-2019)

Sample solution: ▲Nominally 0.1 mg/mL of nifedipine in *Mobile phase* from *Sample stock solution*. Pass through a suitable filter of 0.45-µm pore size.▲ (USP 1-May-2019)

Chromatographic system

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

Mode: LC

Detector: UV 265 nm.

▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2019)

Columns

Guard: Packing L1

Analytical: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 25 µL

▲**Run time:** NLT 1.5 times the retention time of nifedipine▲ (USP 1-May-2019)

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 Capsules taken:

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

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

r_S = peak response of nifedipine 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⟩**

Medium: Simulated gastric fluid TS (without pepsin); 900 mL

Apparatus 2: 50 rpm

Time: 20 min

Standard solution: Dissolve a quantity of USP Nifedipine RS in an amount of methanol not exceeding 2% of the final volume, and dilute with *Medium* to obtain a solution of a known suitable concentration.

Sample solution: Pass a portion of solution under test through a suitable filter, and dilute as needed with *Medium*, in comparison with the *Standard solution*. Filters must be checked for absorptive loss of nifedipine.

Instrumental conditions

Mode: UV

Analytical wavelength: 340 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$) dissolved by using UV absorbances at the specified wavelength.

Tolerances: NLT 80% (*Q*) of the labeled amount of nifedipine ($C_{17}H_{18}N_2O_6$) is dissolved.

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meet the requirements▲ (USP 1-May-2019)

IMPURITIES

Change to read:

• **Organic Impurities:** Protect ▲all solutions containing nifedipine▲ (USP 1-May-2019) from actinic light. Conduct this test promptly after preparation of the *Standard solution* and the *Sample solution*.

Mobile phase, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

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

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

Standard stock solution B: 1 mg/mL of USP Nifedipine Nitrophenylpyridine Analog RS in methanol

Standard solution B: 6 µg/mL of USP Nifedipine Nitrophenylpyridine Analog RS in *Mobile phase* from *Standard stock solution B*

Standard stock solution C: 1 mg/mL of USP Nifedipine Nitrosophenylpyridine Analog RS in methanol

Standard solution C: 1.5 µg/mL of USP Nifedipine Nitrosophenylpyridine Analog RS in *Mobile phase* from *Standard stock solution C*

Standard solution D: Mixture of *Standard solution B*, *Standard solution C*, and *Mobile phase* (1:1:1)

System suitability solution: Mixture of *Standard solution A*, *Standard solution B*, and *Standard solution C* (1:1:1) ▲▲ (USP 1-May-2019)

System suitability

Sample: *System suitability solution*

Suitability requirements

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

Relative standard deviation: NMT 10% for each nifedipine nitrophenylpyridine analog and nifedipine nitrosophenylpyridine analog

Analysis

Samples: *Sample solution* and *Standard solution D*

Calculate the percentage of nifedipine nitrophenylpyridine analog and nifedipine nitrosophenylpyridine analog in the portion of Capsules taken:

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

r_U = peak response of nifedipine nitrophenylpyridine analog or nifedipine nitrosophenylpyridine analog from the *Sample solution*

r_S = peak response of nifedipine nitrophenylpyridine analog or nifedipine nitrosophenylpyridine analog from *Standard solution D*

C_S = concentration of the appropriate USP Nifedipine Nitrophenylpyridine Analog RS or USP Nifedipine Nitrosophenylpyridine Analog RS in *Standard solution D* (mg/mL)

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

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Nifedipine ▲nitrophenylpyridine▲ (USP 1-May-2019) analog	0.8	2.0
Nifedipine ▲nitrosophenylpyridine▲ (USP 1-May-2019) analog	0.9	0.5
Nifedipine	1.0	—

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight, light-resistant containers at ▲controlled room temperature.▲ (USP 1-May-2019)

• **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

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NIFEDIPINE CAPSULES	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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