

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Feb-2025
 Document Type: USP Monographs
 DocId: GUID-C3EA9EE6-2613-467C-941C-F08E4809F499_8_en-US
 DOI: https://doi.org/10.31003/USPNF_M3807_08_01
 DOI Ref: 9q9h3

© 2025 USPC
 Do not distribute

Nicardipine Hydrochloride Injection

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb-nicardipine-hcl-inj-20250131>.

DEFINITION

Nicardipine Hydrochloride Injection is a sterile solution of Nicardipine Hydrochloride. It contains NLT 90.0% and NMT 110.0% of the labeled amount of nicardipine hydrochloride ($C_{26}H_{29}N_3O_6 \cdot HCl$).

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: 1.36 g/L of [monobasic potassium phosphate](#) in [water](#)

Mobile phase: [Methanol](#) and *Buffer* (80:20)

Diluent: [Acetonitrile](#) and *Buffer* (50:50)

Standard solution: 0.1 mg/mL of [USP Nicardipine Hydrochloride RS](#) in *Diluent*. Sonication may be used to aid in dissolution. Pass through a suitable filter of 0.45- μ m pore size. Discard the first 2–3 mL of the filtrate.

Sample solution: Nominally 0.1 mg/mL of nicardipine hydrochloride in *Diluent* from a suitable volume of Injection. Pass through a suitable filter of 0.45- μ m pore size. Discard the first 2–3 mL of filtrate. [NOTE—The *Sample solution* is stable for about 26 h.]

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 μ L

Run time: NLT 2 times the retention time of nicardipine

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 nicardipine hydrochloride ($C_{26}H_{29}N_3O_6 \cdot HCl$) in the portion of Injection taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• LIMIT OF *N*-BENZYL-*N*-METHYL-ETHANOLAMINE

Solution A: Dissolve 2.80 g of [sodium perchlorate monohydrate](#) in 1 L of [water](#). Adjust with [perchloric acid](#) to a pH of 2.5.

Solution B: [Acetonitrile](#) and [methanol](#) (50:50)

Diluent: [Acetonitrile](#) and [water](#) (20:80)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
10	82	18
12	20	80
22	20	80
24	95	5
32	95	5

Standard solution: 2.5 µg/mL of [USP *N*-Benzyl-*N*-methyl-ethanolamine RS](#) in *Diluent* prepared as follows. To a suitable amount of [USP *N*-Benzyl-*N*-methyl-ethanolamine RS](#), add *Diluent* to 70% of the final volume. Sonicate to dissolve. Cool, and dilute with *Diluent* to volume. Pass the solution through a suitable filter of 0.45-µm pore size.

Sample solution: Nominally 0.5 mg/mL of nicardipine hydrochloride in *Diluent* from a suitable volume of Injection. Pass the solution through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Temperatures

Autosampler: 10°

Column: 30°

Flow rate: 1.5 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of *N*-benzyl-*N*-methyl-ethanolamine in the portion of Injection taken:

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

r_U = peak response of *N*-benzyl-*N*-methyl-ethanolamine from the *Sample solution*

r_S = peak response of *N*-benzyl-*N*-methyl-ethanolamine from the *Standard solution*