



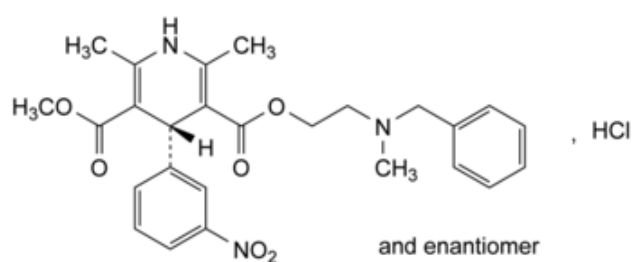
Edition: BP 2025 (Ph. Eur. 11.6 update)

Nicardipine Hydrochloride



[General Notices](#)

(Ph. Eur. monograph 2776)



C₂₆H₃₀ClN₃O₆ 516.0 54527-84-3

Action and use

Calcium channel blocker.

Ph Eur

DEFINITION

3-[2-[Benzyl(methyl)amino]ethyl] 5-methyl (4*RS*)-2,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate hydrochloride.

Content

99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance

Pale yellow or pale greenish-yellow, crystalline powder.

Solubility

Slightly soluble in water, soluble in methanol, sparingly soluble in ethanol (96 per cent).

It shows polymorphism ([5.9](#)).

IDENTIFICATION

First identification: A, C.

Second identification: B.

A. Infrared absorption spectrophotometry ([2.2.24](#)).

Comparison [nicardipine hydrochloride CRS](#).

If the spectra obtained in the solid state show differences, dissolve the substance to be examined and the reference substance separately in the minimum volume of [methanol R](#), evaporate to dryness and record new spectra using the residues.

B. Thin-layer chromatography ([2.2.27](#)).

Test solution Dissolve 10 mg of the substance to be examined in [methanol R](#) and dilute to 10.0 mL with the same solvent.

Reference solution Dissolve 10 mg of [nicardipine hydrochloride CRS](#) in [methanol R](#) and dilute to 10.0 mL with the same solvent.

Plate [TLC silica gel F₂₅₄ plate R](#).

Mobile phase [cyclohexane R](#), [ethyl acetate R](#) (40:60 V/V).

Application 2 µL.

Development Over 3/4 of the plate.

Drying In air.

Detection A Examine in ultraviolet light at 254 nm.

Results A The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.

Detection B Spray with [iodoplatinate reagent R](#); examine the chromatogram in daylight.

Results B The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.

C. Dissolve 30 mg in 10 mL of [water R](#) and shake vigorously. The solution gives reaction (a) of chlorides ([2.3.1](#)).

TESTS

Related substances

Liquid chromatography ([2.2.29](#)). *Carry out the test protected from light.*

Test solution Dissolve 50.0 mg of the substance to be examined in the mobile phase and dilute to 25.0 mL with the mobile phase.

Reference solution (a) Dilute 1.0 mL of the test solution to 50.0 mL with the mobile phase. Dilute 1.0 mL of this solution to 20.0 mL with the mobile phase.

Reference solution (b) Dissolve 4 mg of [nicardipine for system suitability CRS](#) (containing impurities A, B and C) in 2 mL of the mobile phase.

Column:

- *size:* $l = 0.15$ m, $\varnothing = 4.6$ mm;
- *stationary phase:* [end-capped octadecylsilyl silica gel for chromatography R](#) (5 μ m);
- *temperature:* 30 °C.

Mobile phase Mix 35 volumes of [acetonitrile R](#) and 65 volumes of a 1.5 g/L solution of [perchloric acid R](#).

Flow rate 1.5 mL/min.

Detection Spectrophotometer at 254 nm.

Injection 10 μ L.

Run time 4 times the retention time of nicardipine.

Identification of impurities Use the chromatogram obtained with reference solution (b) to identify the peaks due to impurities A, B and C.

Relative retention With reference to nicardipine (retention time = about 8 min): impurity B = about 0.5; impurity A = about 0.8; impurity C = about 2.1.

System suitability Reference solution (b):

- *resolution:* minimum 1.5 between the peaks due to impurity A and nicardipine.

Calculation of percentage contents:

- for each impurity, use the concentration of nicardipine hydrochloride in reference solution (a).

Limits:

- *impurity B:* maximum 0.5 per cent;
- *impurities A, C:* for each impurity, maximum 0.15 per cent;
- *unspecified impurities:* for each impurity, maximum 0.10 per cent;
- *total:* maximum 1.0 per cent;
- *reporting threshold:* 0.05 per cent.

Loss on drying (2.2.32)

Maximum 1.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

Sulfated ash (2.4.14)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

<https://nhathuocngocanh.com/bp/>

Dissolve 0.400 g in 50 mL of ethanol (96 per cent) R. Titrate with 0.1 M sodium hydroxide, determining the end-point potentiometrically (2.2.20).

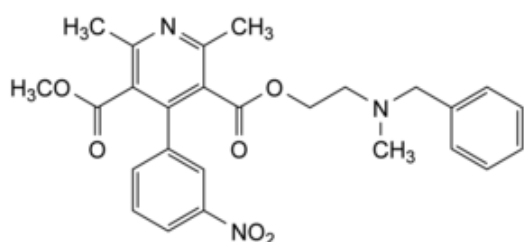
1 mL of 0.1 M sodium hydroxide is equivalent to 51.60 mg of $C_{26}H_{30}ClN_3O_6$.

STORAGE

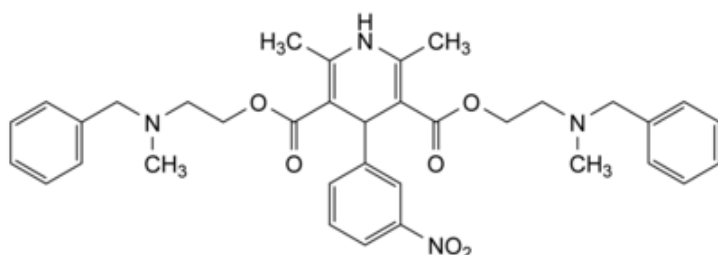
In an airtight container, protected from light.

IMPURITIES

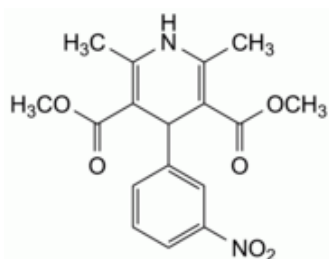
Specified impurities A, B, C.



A. 3-[2-[benzyl(methyl)amino]ethyl] 5-methyl 2,6-dimethyl-4-(3-nitrophenyl)pyridine-3,5-dicarboxylate,



B. bis[2-[benzyl(methyl)amino]ethyl] 2,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate,



C. dimethyl 2,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate.

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