



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

Nifedipine Prolonged-release Tablets

[General Notices](#)

Prolonged-release Nifedipine Tablets

Nifedipine Prolonged-release Tablets from different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable unless otherwise justified and authorised.

Action and use

Calcium channel blocker.

DEFINITION

Nifedipine Prolonged-release Tablets contain Nifedipine. They are formulated so that the medicament is released over a period of several hours.

PRODUCTION

A suitable dissolution test is carried out to demonstrate the appropriate release of Nifedipine. The dissolution profile reflects the *in vivo* performance which in turn is compatible with the dosage schedule recommended by the manufacturer.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of nifedipine, $C_{17}H_{18}N_2O_6$

95.0 to 105.0% of the stated amount.

Carry out all the following procedures in the dark or under long-wavelength light (greater than 420 nm). Prepare solutions immediately before use and protect them from light.

IDENTIFICATION

A. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions.

- (1) Shake a quantity of the powdered tablets containing 20 mg of Nifedipine with 100 mL of a solution containing equal volumes of [dichloromethane](#) and [methanol](#) and filter (Whatman GF/C is suitable).
- (2) 0.02% w/v of [nifedipine BPCRS](#) in equal volumes of [dichloromethane](#) and [methanol](#).
- (3) Equal volumes of solution (1) and solution (2).

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel \$F_{254}\$](#) (Merck silica gel 60 F_{254} plates are suitable).
- (b) Use the mobile phase as described below.
- (c) Apply 20 μ L of each solution.
- (d) Develop the plate to 15 cm in an unsaturated tank.
- (e) After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm\)](#).

MOBILE PHASE

40 volumes of [ethyl acetate](#) and 60 volumes of [cyclohexane](#).

The test is not valid unless the chromatogram obtained with solution (3) appears as a single spot.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position and size to that in the chromatogram obtained with solution (2).

B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

TESTS

Related substances

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions.

- (1) Shake a quantity of the powdered tablets containing 50 mg of Nifedipine in 15 mL of [methanol](#), dilute to 25 mL with [methanol](#) and filter. Dilute 1 volume of the resulting solution with 1 volume of the mobile phase.
- (2) Dilute 1 volume of solution (1) to 100 volumes with the mobile phase and dilute 1 volume of the resulting solution to 5 volumes with the mobile phase.
- (3) 0.0005% w/v of [dimethyl-2,6-dimethyl-4-\(2-nitrophenyl\)pyridine-3,5-dicarboxylate BPCRS](#) in the mobile phase.
- (4) 0.0005% w/v of [dimethyl-2,6-dimethyl-4-\(2-nitrosophenyl\)pyridine-3,5-dicarboxylate BPCRS](#) in the mobile phase.
- (5) Dilute 1 volume of solution (1) to 100 volumes with the mobile phase and dilute 1 volume of the resulting solution with 1 volume of solution (3) and 1 volume of solution (4).
- (6) Dilute 1 volume of solution (2) to 4 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm) (Lichrosorb RP18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 235 nm.
- (f) Inject 20 µL of each solution.

MOBILE PHASE

9 volumes of [acetonitrile](#), 36 volumes of [methanol](#) and 55 volumes of [water](#).

SYSTEM SUITABILITY

The test is not valid unless in the chromatogram obtained with solution (5):

the [resolution factor](#) between the peaks due to dimethyl-2,6-dimethyl-4-(2-nitrophenyl)pyridine-3,5-dicarboxylate and dimethyl-2,6-dimethyl-4-(2-nitrosophenyl)pyridine-3,5-dicarboxylate is at least 1.5;

the [resolution factor](#) between the peaks due to dimethyl-2,6-dimethyl-4-(2-nitrosophenyl)pyridine-3,5-dicarboxylate and nifedipine is at least 1.5.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to dimethyl-2,6-dimethyl-4-(2-nitrophenyl)pyridine-3,5-dicarboxylate is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (0.5%);

the area of any peak corresponding to dimethyl-2,6-dimethyl-4-(2-nitrosophenyl)pyridine-3,5-dicarboxylate is not greater than the area of the principal peak in the chromatogram obtained with solution (4) (0.5%);

the area of any other [secondary peak](#) is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the areas of any other [secondary peaks](#) is not greater than 5 times the area of the principal peak in the chromatogram obtained with solution (2) (1.0%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (6) (0.05%).

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#).

- (1) Scratch the film coating on 10 whole tablets, add 450 mL of [methanol](#), mix with the aid of ultrasound until completely disintegrated, add sufficient [methanol](#) to produce 500 mL and filter. Dilute a volume of the resulting filtrate with sufficient mobile phase to produce a solution containing 0.02% w/v of Nifedipine.
- (2) 0.02% w/v of [nifedipine BPCRS](#) in the mobile phase.
- (3) 0.0003% w/v of [nifedipine BPCRS](#), 0.0002% w/v of [dimethyl-2,6-dimethyl-4-\(2-nitrophenyl\)pyridine-3,5-dicarboxylate BPCRS](#) and 0.0002% w/v of [dimethyl-2,6-dimethyl-4-\(2-nitrosophenyl\)pyridine-3,5-dicarboxylate BPCRS](#) in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless in the chromatogram obtained with solution (3):

the [resolution factor](#) between the peaks due to dimethyl-2,6-dimethyl-4-(2-nitrophenyl)pyridine-3,5-dicarboxylate and dimethyl-2,6-dimethyl-4-(2-nitrosophenyl)pyridine-3,5-dicarboxylate is at least 1.5;

the [resolution factor](#) between the peaks due to dimethyl-2,6-dimethyl-4-(2-nitrosophenyl)pyridine-3,5-dicarboxylate and nifedipine is at least 1.5.

DETERMINATION OF CONTENT

Calculate the content of $C_{17}H_{18}N_2O_6$ in the tablets using the declared content of $C_{17}H_{18}N_2O_6$ in [nifedipine BPCRS](#).

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Nifedipine.