



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

Solifenacin Oral Solution

[General Notices](#)

Action and use

Muscarinic M₃ receptor antagonist; anticholinergic.

DEFINITION

Solifenacin Oral Solution is a solution of [Solifenacin Succinate](#) in a suitable flavoured vehicle.

The oral solution complies with the requirements stated under [Oral Liquids](#) and with the following requirements.

Content of solifenacin succinate, C₂₇H₃₂N₂O₆

95.0 to 105.0% of the stated amount.

IDENTIFICATION

In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 210 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

TESTS

Related substances

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

Solution A 20 volumes of [acetonitrile R1](#) and 30 volumes of 0.1M [hydrochloric acid](#).

(1) To a quantity of the oral solution containing 6 mg of Solifenacin Succinate add 30 mL of solution A, shake and dilute to 50 mL with solution A.

(2) Dilute 1 volume of solution (1) to 100 volumes with solution A. Further dilute 1 volume of this solution to 5 volumes with solution A.

(3) To 10 mg of [solifenacin succinate BPCRS](#) add 1 mL of [hydrogen peroxide \(30%\)](#), 5 mL of 0.1M [sodium hydroxide](#), 10 mL of [water](#) and 5 mL of [acetonitrile](#). Stir uncovered for 10 minutes (generation of impurity I). Add 1 volume of this solution to 2.5 volumes of solution (1) and dilute to 25 volumes with solution A.

(4) 0.1% w/v of [solifenacin succinate impurity standard BPCRS](#) (containing impurities A and 1) in solution A.

CHROMATOGRAPHIC CONDITIONS

- Use a stainless steel column (15 cm × 4.6 mm) packed with [end-capped octadecylsilyl silica gel for chromatography](#) (3.5 µm) (Waters XTerra MS C18 is suitable).
- Use gradient elution and the mobile phase described below.
- Use a flow rate of 1 mL per minute.
- Use a column temperature of 40°.
- Use an autosampler temperature of 5°.
- Use a detection wavelength of 210 nm.
- Inject 15 µL of each solution.

MOBILE PHASE

Mobile phase A 20 volume of [acetonitrile R1](#) and 80 volumes of a 0.05M [ammonium dihydrogen orthophosphate](#) solution previously adjusted to pH 2.4 with [orthophosphoric acid](#).

Mobile phase B [Acetonitrile R1](#).

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-25	95-90	5-10	linear gradient
25-40	90-75	10-25	linear gradient
40-41	75-50	25-50	linear gradient
41-65	50	50	isocratic
65-66	50-95	50-5	linear gradient
66-75	95	5	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to solifenacin and impurity I is at least 2.0.

CALCULATION OF IMPURITIES

For each impurity, use the concentration of solifenacin succinate in solution (2).

For the reporting threshold, use the concentration of solifenacin succinate in solution (2).

For peak identification, use solutions (3) and (4).

Solifenacin succinate retention time: about 26 minutes.

Relative retention: impurity A, about 0.2; impurity 1, about 0.5; impurity I, about 1.1.

Correction factor: impurity A, multiply by 0.7.

LIMITS

- unspecified impurities: for each impurity, not more than 0.2%;
- total impurities: not more than 0.5%;
- reporting threshold: 0.1%.

ASSAY

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

- To a weighed amount of the oral solution containing 6 mg of Solifenacin Succinate, add in 30 mL, shake and dilute to produce 50 mL. Dilute 1 volume of this solution to 10 volumes.
- 0.0012% w/v of [solifenacin succinate BPCRS](#).
- 0.0012% w/v of [solifenacin succinate BPCRS](#) and 0.00024% w/v of [propyl 4-hydroxybenzoate](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (15 cm × 4.6 mm) packed with [end-capped octadecylsilyl amorphous organosilica polymer for chromatography](#) (3.5 µm) (Waters XTerra MS C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1 mL per minute.
- (d) Use a column temperature of 40°.
- (e) Use an autosampler temperature of 5°.
- (f) Use a detection wavelength of 210 nm.
- (g) Inject 25 µL of each solution.

MOBILE PHASE

30 volumes of [acetonitrile R1](#) and 70 volumes of a 0.05M [ammonium dihydrogen orthophosphate](#) solution previously adjusted to pH 2.4 with [orthophosphoric acid](#).

When the chromatograms are recorded under the prescribed conditions the retention time of the solifenacin is about 11 minutes.

SYSTEM SUITABILITY

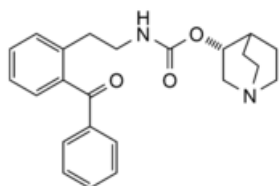
The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to solifenacin and propyl 4-hydroxybenzoate is at least 1.5.

DETERMINATION OF CONTENT

Determine the [weight per mL](#) of the oral solution, [Appendix V G](#), and calculate the content of C₂₇H₃₂N₂O₆, weight in volume, using the declared content of C₂₇H₃₂N₂O₆ in [solifenacin succinate BPCRS](#).

IMPURITIES

The impurities limited by the requirements of this monograph include impurity I listed under [Solifenacin Succinate](#) and:



1. (+)-(R)-quinuclidin-3-yl [2-(2-benzoylphenyl)ethyl]carbamate