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Rifampicin Oral Suspension

General Notices

Details for the public consultation of this monograph are as follows:

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Notes:	REVISED Identification, Related Substances and Assay updated If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required.

Action and use

Rifamycin antituberculosis drug.

DEFINITION

Rifampicin Oral Suspension is a suspension of Rifampicin suitable vehicle.

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

Content of rifampicin, $C_{43}H_{58}N_4O_{12}$

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

Acidity

pH, 4.2 to 4.8, [Appendix V L](#).

Related substances

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions prepared in the solvent mixture described below.

To 10 volumes of a 21.01% w/v solution of [citric acid](#) add 23 volumes of a 13.61% w/v solution of [potassium dihydrogen orthophosphate](#), 77 volumes of a 17.42% w/v solution of [dipotassium hydrogen orthophosphate](#), 250 volumes of [acetonitrile](#) and 640 volumes of [water](#) and mix. Prepare the solutions immediately before use.

(1) Add 5 mL of [water](#) to a quantity of the oral suspension containing 20 mg of Rifampicin and extract with four 10-mL quantities of [dichloromethane](#), filter the combined extracts and evaporate to dryness at a temperature not exceeding 40°. Dissolve the residue in 10 mL of [acetonitrile](#) and dilute 5 mL of the solution to 50 mL with the solvent mixture.

(2) Dilute 1 volume of solution (1) to 100 volumes.

(3) 0.0003% w/v of [rifampicin quinone EPCRS](#) (impurity A).

(4) 0.0002% w/v of [rifampicin N-oxide BPCRS](#) (impurity B).

(5) 0.001% w/v of [3-formylrifamycin SV BPCRS](#) (impurity 1).

(6) Dilute 1 volume of solution (3) to 4 volumes and mix 1 volume of the resulting solution with 1 volume of solution (2).

(7) Dilute 1 volume of solution (2) to 10 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 cm × 4.6 mm) packed with [octylsilyl silica gel for chromatography](#) (5 µm) (Partisil C8 is suitable).

(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 1.5 mL per minute.

(d) Use an ambient column temperature.

(e) Use an autosampler temperature of 5°

(f) Use a detection wavelength of 254 nm.

(g) Inject 20 µL of each solution.

(h) For solution (1) allow the chromatography to proceed for at least 3 times the retention time of the peak due to rifampicin.

MOBILE PHASE

35 volumes of [acetonitrile](#) and 65 volumes of a solution containing 0.1% v/v of [orthophosphoric acid](#), 0.19% w/v of [sodium perchlorate](#), 0.59% w/v of [citric acid](#) and 2.09% w/v of [potassium dihydrogen orthophosphate](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (6), the [resolution](#) between the two principal peaks is at least 4.0. If necessary, adjust the concentration of [acetonitrile](#) in the mobile phase.

CALCULATION OF IMPURITIES

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

For the reporting threshold, use the concentration of rifampicin in solution (7).

For peak identification, use solutions (3), (4) and (5).

Rifampicin retention time: about 12 minutes.

Relative retention: impurity A, about 0.6; impurity B, about 1.3; impurity 1, about 3.1.

Disregard any peaks eluting before the peak due to impurity A.

LIMITS

- impurity A: not more than 1.5%;
- impurity B: not more than 1.0%;
- impurity 1: not more than 5%;
- unspecified impurities: for each impurity, not more than 1.0%;
- total unspecified impurities: not more than 3.0%;
- reporting threshold: 0.1%.

ASSAY

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions prepared in solvent mixture described below.

To 10 volumes of a 21.01% w/v solution of [citric acid](#) add 23 volumes of a 13.61% w/v solution of [potassium dihydrogen orthophosphate](#), 77 volumes of a 17.42% w/v solution of [dipotassium hydrogen orthophosphate](#), 250 volumes of [acetonitrile](#) and 640 volumes of [water](#) and mix. Prepare the solutions immediately before use. .

(1) Add 5 mL of [water](#) to a quantity of the oral suspension containing 30 mg of Rifampicin and extract with eight 10 mL quantities of [dichloromethane](#), evaporate to dryness at a temperature not exceeding 40°. Dissolve the residue in 10 mL *solvent mixture* and dilute 5 mL of the solution to 50 mL with the solvent mixture. Dilute 1 volume of this solution to 10 volumes with the solvent mixture.

(2) 0.003% [Rifampicin BPCRS](#).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related Substances may be used, excluding (h).

DETERMINATION OF CONTENT

Calculate the total content of rifampicin, $C_{43}H_{58}N_4O_{12}$, in the capsules from the chromatograms obtained and using the declared content of $C_{43}H_{58}N_4O_{12}$, in [Rifampicin BPCRS](#).

IMPURITIES

The impurities limited by the requirements of this monograph include A and B listed under [Rifampicin](#) and:

 1. 3-formylrifamycin SV

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