



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

## Trimethoprim Oral Suspension

### [General Notices](#)

### Action and use

Dihydrofolate reductase inhibitor; antibacterial.

### DEFINITION

Trimethoprim Oral Suspension is a suspension of Trimethoprim in a suitable flavoured vehicle.

*The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements.*

### Content of trimethoprim, $C_{14}H_{18}N_4O_3$

90.0 to 110.0% of the stated amount.

### IDENTIFICATION

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

(1) Add 15 mL of 0.1M [sodium hydroxide](#) to a quantity of the oral suspension containing 10 mg of Trimethoprim, extract with 50 mL of [dichloromethane](#) and wash the dichloromethane extract with two 10-mL quantities of 0.01M [sodium hydroxide](#). Retain the sodium hydroxide solutions and repeat the extraction procedure with a further three 50-mL quantities of [dichloromethane](#), washing the extracts each time with the same two 10-mL quantities of 0.01M [sodium hydroxide](#). Evaporate the combined dichloromethane extracts until about 2 mL remains, transfer the residue to a 10-mL graduated flask with the aid of [dichloromethane](#), add sufficient [dichloromethane](#) to produce 10 mL and mix well.

(2) 0.1% w/v of [trimethoprim BPCRS](#) in [dichloromethane](#).

### CHROMATOGRAPHIC CONDITIONS

- Use as the coating [silica gel GF<sub>254</sub>](#).
- Use the mobile phase as described below.
- Apply 10 µL of each solution.
- Develop the plate to 15 cm.
- After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm\)](#).

### MOBILE PHASE

2 volumes of 13.5M [ammonia](#), 8 volumes of [methanol](#) and 90 volumes of [dichloromethane](#).

### CONFIRMATION

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

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

## TESTS

### Acidity or alkalinity

pH, 6.5 to 7.5, [Appendix V L](#).

## ASSAY

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

- (1) Add 10 mL of [methanol](#) and 10 mL of the mobile phase to a weighed quantity of the oral suspension containing 10 mg of Trimethoprim, mix with the aid of ultrasound for 5 minutes and add sufficient of the mobile phase to produce 50 mL, mix and filter.
- (2) 0.02% w/v of [trimethoprim BPCRS](#) in [methanol](#).

### CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (10 μm) (Lichrosorb RP 18 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 260 nm.
- (f) Inject 20 μL of each solution.

### MOBILE PHASE

225 volumes of 0.003M [tetrabutylammonium bromide](#) in [water](#), 225 volumes of a buffer solution prepared as described below and 550 volumes of [methanol](#).

For the buffer solution dissolve 1.36 g of [sodium acetate](#) and 23.4 g of [sodium dihydrogen orthophosphate](#) in 450 mL of [water](#), adjust the pH of the mixture, if necessary, to 5.0 with 0.1M [glacial acetic acid](#) or 0.1M [sodium hydroxide](#) and add sufficient [water](#) to produce 500 mL.

### DETERMINATION OF CONTENT

Determine the [weight per mL](#) of the oral suspension, [Appendix V G](#), and calculate the content of  $C_{14}H_{18}N_4O_3$ , weight in volume, using the declared content of  $C_{14}H_{18}N_4O_3$  in [trimethoprim BPCRS](#).