



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

Temazepam Oral Solution

[General Notices](#)

Action and use

Benzodiazepine.

DEFINITION

Temazepam Oral Solution is a solution of Temazepam in a suitable flavoured vehicle.

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

Content of temazepam, C₁₆H₁₃ClN₂O₂

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Dilute a quantity of the oral solution with sufficient 0.1M [methanolic hydrochloric acid](#) to produce a solution containing 0.001% w/v of Temazepam. The [light absorption](#) of the resulting solution, [Appendix II B](#), in the range 210 to 400 nm exhibits three maxima, at 238 nm, 283 nm and 358 nm.

B. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using a silica gel F₂₅₄ pre-coated plate (Merck silica gel 60 F₂₅₄ plates are suitable) and a mixture of 50 volumes of [cyclohexane](#), 40 volumes of [chloroform](#) and 10 volumes of [diethylamine](#) as the mobile phase. Apply separately to the plate 2 µL of each of the following solutions. For solution (1) add 5 mL of [water](#) to a quantity of the oral solution containing 10 mg of Temazepam and extract with two 10-mL quantities of [ether](#). Evaporate the combined ether extracts almost to dryness and dissolve the residue in 2 mL of [acetone](#). Solution (2) contains 0.5% w/v of [temazepam BPCRS](#) in [acetone](#). After removal of the plate, allow it to dry in air and examine under [ultraviolet light \(254 nm\)](#). The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

C. In the Assay, the chromatogram obtained with solution (2) exhibits a peak with the same retention time as that due to temazepam in the chromatogram obtained with solution (1).

TESTS

Alkalinity

pH, 7.3 to 8.3, [Appendix V L](#).

6-Chloro-1,4-dihydro-1-methyl-4-phenylquinazolin-4-ol

Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using a silica gel pre-coated plate (Merck silica gel 60 F₂₅₄ plates are suitable) and a mixture of 92.5 volumes of [chloroform](#) and 7.5 volumes of [methanol](#) as the mobile phase but allowing the solvent front to ascend 12 cm above the line of application. Apply separately to the plate 10 µL of each of the

following solutions. For solution (1) add 5 mL of [water](#) to a quantity of the oral solution containing 10 mg of Temazepam and extract with two 10-mL quantities of [ether](#). Evaporate the combined ether extracts almost to dryness and dissolve the residue in 1 mL of [acetone](#). Solution (2) contains 0.010% w/v of [6-chloro-1,4-dihydro-1-methyl-4-phenylquinazolin-4-ol BPCRS](#). After removal of the plate, allow it to dry in a current of warm air and examine under [ultraviolet light \(365 nm\)](#). In the chromatogram obtained with solution (1) any spot corresponding to 6-chloro-1,4-dihydro-1-methyl-4-phenylquinazolin-4-ol is not more intense than the spot in the chromatogram obtained with solution (2).

5-Chloro-2-methylaminobenzophenone

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions. Solution (1) contains 0.00050% w/v of [5-chloro-2-methylaminobenzophenone BPCRS](#) in [methanol \(50%\)](#). For solution (2) dilute a quantity of the oral solution with sufficient [methanol \(50%\)](#) to produce a solution containing 0.020% w/v of Temazepam.

The chromatographic procedure may be carried out using (a) a stainless steel column (25 cm × 5 mm) packed with [end-capped octadecylsilyl silica gel for chromatography \(5 µm\)](#) (Lichrosorb RP-18 is suitable), (b) a mixture of 75 volumes of [methanol](#), 25 volumes of [water](#) and 0.03 volume of [diethylamine](#) as the mobile phase with a flow rate of 1.5 mL per minute and (c) a detection wavelength of 254 nm.

In the chromatogram obtained with solution (2) the area of any peak corresponding to 5-chloro-2-methylaminobenzophenone is not greater than the area of the peak in the chromatogram obtained with solution (1).

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions. Solution (1) contains 0.02% w/v of [temazepam BPCRS](#) in [methanol \(50%\)](#). For solution (2) add sufficient [methanol \(50%\)](#) to a weighed quantity of the oral solution containing 20 mg of Temazepam to produce 100 mL.

The chromatographic procedure may be carried out using (a) a stainless steel column (20 cm × 4.6 mm) packed with [end-capped octadecylsilyl silica gel for chromatography \(5 µm\)](#) (Hypersil ODS is suitable), (b) a mixture of 60 volumes of [methanol](#), 40 volumes of [water](#) and 0.03 volumes of [diethylamine](#) as the mobile phase with a flow rate of 2 mL per minute and (c) a detection wavelength of 254 nm.

Determine the [weight per mL](#) of the oral solution, [Appendix V G](#), and calculate the content of $C_{16}H_{13}ClN_2O_2$, weight in volume, using the declared content of $C_{16}H_{13}ClN_2O_2$ in [temazepam BPCRS](#).

STORAGE

Temazepam Oral Solution should be protected from light.