



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

Temazepam Tablets

[General Notices](#)

Action and use

Benzodiazepine.

DEFINITION

Temazepam Tablets contain Temazepam.

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

Content of temazepam, $C_{16}H_{13}ClN_2O_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. The [light absorption](#), [Appendix II B](#), in the range 210 to 400 nm of the final solution obtained in the Assay exhibits two maxima at 230 nm and at 315 nm and a shoulder at 250 nm.
- B. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using a silica gel F₂₅₄ precoated plate (Merck silica gel 60 F₂₅₄ plates are suitable) and a mixture of 10 volumes of [diethylamine](#) and 90 volumes of [ether](#) as the mobile phase. Apply separately to the plate 5 µl of each of the following solutions. For solution (1) shake a quantity of the powdered tablets containing 20 mg of Temazepam for 5 minutes with 20 ml of [methanol](#) and filter. Solution (2) contains 0.10% w/v of [temazepam BPCRS](#) in [methanol](#). After removal of the plate, allow it to dry in air and examine under [ultraviolet light \(254 nm\)](#). The chromatogram obtained with solution (1) exhibits a spot which corresponds to the spot in the chromatogram obtained with solution (2).

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the [dissolution test for tablets and capsules](#), Appendix XII B1, using Apparatus 2. Use as the medium 900 ml of [0.1M hydrochloric acid](#) and rotate the paddle at 50 revolutions per minute. Measure the [absorbance](#) of a layer of suitable thickness of the filtered sample, suitably diluted if necessary, with [0.1M hydrochloric acid](#), at the maximum at 237 nm, [Appendix II B](#), using 0.1M [hydrochloric acid](#) in the reference cell. Measure the [absorbance](#) of a suitable solution of [temazepam BPCRS](#) in the dissolution medium and calculate the total content of temazepam, $C_{16}H_{13}ClN_2O_2$, in the medium from the absorbances obtained and from the declared content of $C_{16}H_{13}ClN_2O_2$ in [temazepam BPCRS](#).

Related substances

Carry out the test protected from light. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using a silica gel F₂₅₄ precoated plate (Merck silica gel 60 F₂₅₄ plates are suitable) and a mixture of 2 volumes of [methanol](#) and 98 volumes of [dichloromethane](#) as the mobile phase. Apply separately to the plate 20 µl of each of the following solutions, prepared immediately before use, in low-actinic glassware. For solution (1) shake a quantity of the powdered tablets containing 50 mg of Temazepam for 10 minutes with 5 ml of a mixture of equal volumes of [dichloromethane](#) and [methanol](#) and filter. For solution (2) dilute 1 volume of solution (1) to 200 volumes with the same solvent mixture. For solution (3) dilute 2 volumes of solution (2) to 5 volumes with the same solvent mixture. After removal of the plate, allow it to dry in air and examine under [ultraviolet light \(254 nm\)](#). Any [secondary spot](#) in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%) and not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (0.2%).

ASSAY

Carry out the following procedure protected from light. Weigh and powder 20 tablets. Shake a quantity of the powdered tablets containing 20 mg of Temazepam with 75 ml of [methanol](#) for 20 minutes, dilute to 100 ml with the same solvent and filter. Dilute 10 ml of the resulting filtrate to 250 ml with [methanol](#) and measure the [absorbance](#) of the resulting solution at the maximum at about 230 nm, [Appendix II B](#). Calculate the content of C₁₆H₁₃ClN₂O₂ in the tablets from the [absorbance](#) obtained using a 0.0008% w/v solution of [temazepam BPCRS](#) in [methanol](#) and using the declared content of C₁₆H₁₃ClN₂O₂ in [temazepam BPCRS](#).

STORAGE

Temazepam Tablets should be protected from light.