

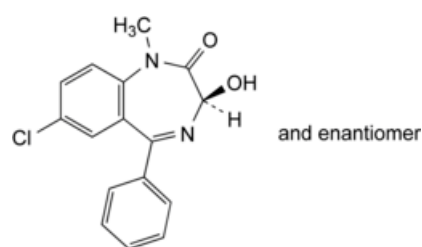


Edition: BP 2025 (Ph. Eur. 11.6 update)

Temazepam

[General Notices](#)

(Ph. Eur. monograph 0954)



$C_{16}H_{13}ClN_2O_2$ 300.7 846-50-4

Action and use

Benzodiazepine.

Preparations

[Temazepam Oral Solution](#)

[Temazepam Tablets](#)

Ph Eur

DEFINITION

(3*RS*)-7-Chloro-3-hydroxy-1-methyl-5-phenyl-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one.

Content

98.0 per cent to 102.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96 per cent).

IDENTIFICATION

Infrared absorption spectrophotometry ([2.2.24](#)).

Comparison [temazepam for ID and assay CRS](#).

TESTS

Related substances

Liquid chromatography ([2.2.29](#)).

Solvent mixture [acetonitrile R](#), mobile phase A (30:70 V/V).

Test solution (a) Dissolve 20.0 mg of the substance to be examined in 6 mL of [acetonitrile R](#) and dilute to 20.0 mL with a 3.9 g/L solution of [ammonium acetate R](#).

Test solution (b) Dilute 1.0 mL of test solution (a) to 10.0 mL with the solvent mixture.

Reference solution (a) Dissolve the contents of a vial of [temazepam for system suitability CRS](#) (containing impurities A, B, E and G) in 300 µL of [acetonitrile R](#); then add 700 µL of mobile phase A.

Reference solution (b) Dilute 1.0 mL of test solution (a) to 100.0 mL with the solvent mixture. Dilute 1.0 mL of this solution to 10.0 mL with the solvent mixture.

Reference solution (c) Dissolve 20.0 mg of [temazepam for ID and assay CRS](#) in 6 mL of [acetonitrile R](#) and dilute to 20.0 mL with a 3.9 g/L solution of [ammonium acetate R](#). Dilute 1.0 mL of the solution to 10.0 mL with the solvent mixture.

Column:

— size: $l = 0.075$ m, $\varnothing = 4.6$ mm;

— stationary phase: [end-capped solid core octadecylsilyl silica gel for chromatography R](#) (2.6 µm).

Mobile phase:

— mobile phase A: 3.9 g/L solution of [ammonium acetate R](#);

— mobile phase B: [acetonitrile R](#);

Time (min)	Mobile phase A (per cent V/V)	Mobile phase B (per cent V/V)
0 - 13	70	30
13 - 25	70 → 30	30 → 70
25 - 28	30	70

Flow rate 1.0 mL/min.

Detection Spectrophotometer at 254 nm.

Injection 20 µL of test solution (a) and reference solutions (a) and (b).

Identification of impurities Use the chromatogram supplied with [temazepam for system suitability CRS](#) and the chromatogram obtained with reference solution (a) to identify the peaks due to impurities A, B, E and G.

Relative retention With reference to temazepam (retention time = about 7 min): impurity B = about 0.57; impurity E = about 0.62; impurity G = about 1.2; impurity A = about 3.

System suitability Reference solution (a):

— [peak-to-valley ratio](#): minimum 1.5, where H_p = height above the baseline of the peak due to impurity G and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to temazepam;

— [resolution](#): minimum 2.0 between the peaks due to impurities B and E.

Calculation of percentage contents:

— *correction factor*: for the calculation of content, multiply the peak area of impurity E by 0.7;

— for each impurity, use the concentration of temazepam in reference solution (b).

Limits:

— *impurity E*: maximum 0.2 per cent;

— *impurity A*: maximum 0.05 per cent;

— *unspecified impurities*: for each impurity, maximum 0.10 per cent;

— *total*: maximum 0.5 per cent;

— *reporting threshold*: 0.05 per cent; do not disregard the peak due to impurity A;

— *reporting threshold for impurity A*: 0.025 per cent.

[Loss on drying \(2.2.32\)](#)

Maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C for 4 h.

[Sulfated ash \(2.4.14\)](#)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Liquid chromatography ([2.2.29](#)) as described in the test for related substances with the following modification.

Injection Test solution (b) and reference solution (c).

Calculate the percentage content of $C_{16}H_{13}ClN_2O_2$ taking into account the assigned content of [temazepam for ID and assay CRS](#).

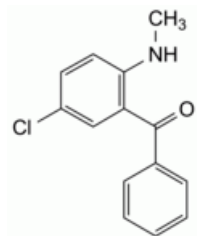
STORAGE

Protected from light.

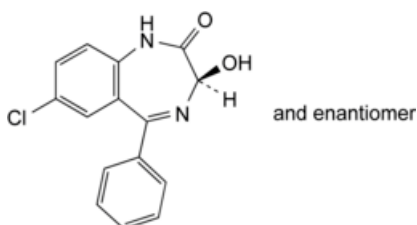
IMPURITIES

Specified impurities A, E.

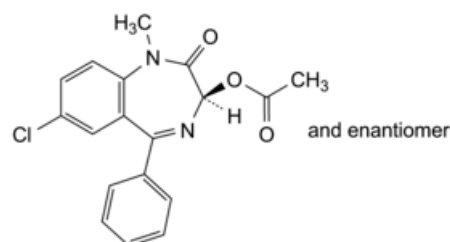
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph [Substances for pharmaceutical use \(2034\)](#). It is therefore not necessary to identify these impurities for demonstration of compliance. See also [5.10. Control of impurities in substances for pharmaceutical use](#)) B, C, D, F, G, H.



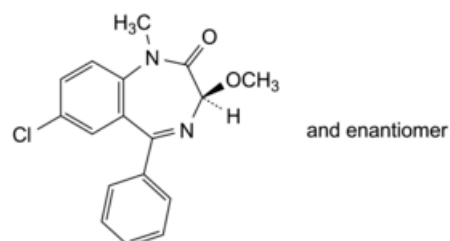
A. [5-chloro-2-(methylamino)phenyl](phenyl)methanone,



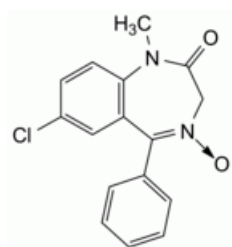
B. (3RS)-7-chloro-3-hydroxy-5-phenyl-1,3-dihydro-2H-1,4-benzodiazepin-2-one (oxazepam),



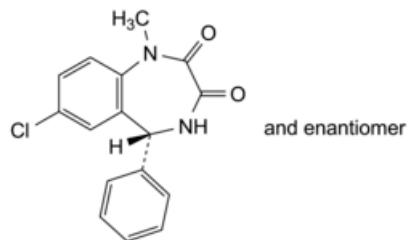
C. (3RS)-7-chloro-1-methyl-2-oxo-5-phenyl-2,3-dihydro-1H-1,4-benzodiazepin-3-yl acetate,



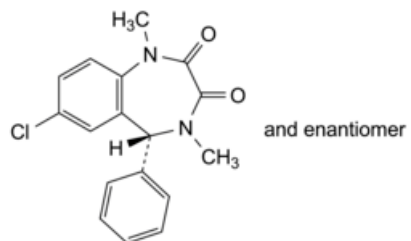
D. (3RS)-7-chloro-3-methoxy-1-methyl-5-phenyl-1,3-dihydro-2H-1,4-benzodiazepin-2-one,



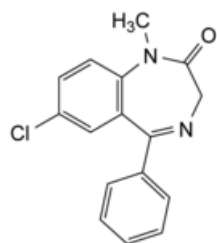
E. 7-chloro-1-methyl-2-oxo-5-phenyl-1,3-dihydro-2H-1,4-benzodiazepine 4-oxide,



F. (5*RS*)-7-chloro-1-methyl-5-phenyl-4,5-dihydro-1*H*-1,4-benzodiazepine-2,3-dione,



G. (5*RS*)-7-chloro-1,4-dimethyl-5-phenyl-4,5-dihydro-1*H*-1,4-benzodiazepine-2,3-dione,



H. 7-chloro-1-methyl-5-phenyl-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one (diazepam).

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