

Status: Effectivity information can only be shown for content published to the website.

Update information can only be shown for content published to the website.

Oxazepam Tablets

General Notices

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

EAG/Panel/Working Party	Medicinal Chemicals 3
Contact Details	michael.whaley@mhra.gov.uk maryna.dmitriieva@mhra.gov.uk sophie.cherrington@mhra.gov.uk bpcom@mhra.gov.uk
Deadline for Comment	31 st December 2026
Target Publication Date (subject to change)	BP 2028
Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. Identification amended. Dissolution the solution concentrations amended to match the lowest strength tablets. Related substances SST resolution amended; autosampler temperature introduced. Assay isocratic elution introduced; autosampler temperature introduced.

Action and use

Benzodiazepine.

DEFINITION

Oxazepam Tablets contain [Oxazepam](#).

The tablets comply with the requirements stated under [Tablets](#) and with the following requirements.

Content of oxazepam, C₁₅H₁₁ClN₂O₂

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Disperse a quantity of the powdered tablets containing 20 mg of Oxazepam in 20 mL of [dichloromethane](#), filter, evaporate to dryness under the stream of nitrogen. The [infrared absorption spectrum](#) of the residue, [Appendix II A](#), is concordant with the reference spectrum of oxazepam (RS 253).

TESTS

Dissolution

Comply with the [dissolution test for tablets and capsules](#), [Appendix XII B1](#). Prepare the solution immediately before use and protect from light.

Solution A: 50 volumes of [water](#) and 50 volumes of [acetonitrile](#).

TEST CONDITIONS

- (a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
- (b) Use 900 mL of 0.1M [hydrochloric acid](#), at a temperature of 37°, as the medium.

PROCEDURE

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

- (1) After 45 minutes withdraw a sample of the medium and filter (a 0.45-µm nylon filter is suitable). Use the filtered medium, diluted with dissolution medium, if necessary, to produce a solution expected to contain about 0.0011% w/v of oxazepam.
- (2) 0.001% w/v of [oxazepam BPCRS](#) in solution A.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Assay may be used.

DETERMINATION OF CONTENT

Calculate the total content of oxazepam, $C_{15}H_{11}ClN_2O_2$, in the medium from the chromatograms obtained and using the declared content of $C_{15}H_{11}ClN_2O_2$ [oxazepam BPCRS](#).

LIMITS

The amount of oxazepam released is not less than 75% (Q) of the stated amount.

Related substances

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions prepared in Solution A. *Prepare the solutions immediately before use and protect from light.*

Solution A: 50 volumes of [water](#) and 50 volumes of [acetonitrile](#).

- (1) To a quantity of powdered tablets containing 75 mg of Oxazepam, add 70 mL of [solution A](#), mix with the aid of ultrasound and dilute with [solution A](#) to produce 100 mL, mix and filter (a 0.45-µm nylon filter is suitable).
- (2) Dilute 1 volume of solution (1) to 500 volumes with solution A.
- (3) Dissolve the contents of a vial of [oxazepam for peak identification CRS](#) in 1.0mL of solution (1).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 4.6mm) packed with *end-capped octadecylsilyl silica gel for chromatography with extended pH range R* (5 µm) (Zorbax Extend C18 is suitable).
- (b) Use gradient 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 an autosampler temperature of 8°.
- (f) Use a detection wavelength of 235 nm.
- (g) Inject 10 µL of each solution.

MOBILE PHASE

Mobile phase A 65 volumes of a 0.35% w/v solution of [dipotassium hydrogen orthophosphate](#) previously adjusted to pH 10.5 with 40 g/L [sodium hydroxide](#).

Mobile phase B [acetonitrile](#).

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-4	75	25	isocratic
4-34	75→25	25→75	linear gradient
34-45	25	75	isocratic
45-50	25→75	75→25	linear gradient
50-60	75	25	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless:

in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to E and A is at least 2.0.

in the chromatogram obtained with solution (2), the [signal-to-noise ratio](#) of the peak due to oxazepam is at least 80.

CALCULATION OF IMPURITIES

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

For the reporting threshold, use the concentration of oxazepam in solution (2).

For peak identification, use solution (3).

Oxazepam retention time: about 15 minutes.

Relative retention(s): impurity E, about 0.7; impurity A, about 0.8; impurity B, about 1.2; impurity C, about 1.4 and impurity D, about 2.0.

Correction factors: impurity A, multiply by 4.0

LIMITS

- unspecified impurities: for each impurity, not more than 0.2%;
- total unspecified impurities: not more than 1.0%;
- reporting threshold: 0.1%.

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions prepared in Solution A. *Prepare the solutions immediately before use and protect from light.*

Solution A: 50 volumes of [water](#) and 50 volumes of [acetonitrile](#)

- (1) To a quantity of powdered tablets containing 15 mg of Oxazepam, add 40 mL of [solution A](#), mix with the aid of ultrasound and dilute to produce 50 mL, mix and filter (0.45-µm nylon filter is suitable). Dilute 1 volume of the filtrate to 10 volumes.
- (2) 0.003% w/v of [oxazepam BPCRS](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 4.6mm) packed with *end-capped octadecylsilyl silica gel for chromatography with extended pH range R* (5 µm) (Zorbax Extend C18 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 an autosampler temperature of 8°.
- (f) Use a detection wavelength of 235 nm.
- (g) Inject 10 µL of each solution.

MOBILE PHASE

Mobile phase 65 volumes of a 0.35% w/v solution of [dipotassium hydrogen orthophosphate](#) previously adjusted to pH 10.5 with 40 g/L [sodium hydroxide](#) and 35 volumes of [acetonitrile](#). Mix and filter through a 0.45 µm filter.

DETERMINATION OF CONTENT

Calculate the content of oxazepam, $C_{15}H_{11}ClN_2O_2$, in the tablets from the chromatograms obtained and using the declared content of $C_{15}H_{11}ClN_2O_2$ in [oxazepam BPCRS](#).

STORAGE

Oxazepam should be kept in an airtight container and protected from light.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under [Oxazepam](#).



DRAFT MONOGRAPH
SUBJECT TO CHANGE