Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-A04E5644-17C6-472E-BB9A-6A1276BF78DC_1_en-US
DOI: https://doi.org/10.31003/USPNF_M59200_01_01
DOI Ref: n8qgz

Oxazepam Capsules

DEFINITION

Oxazepam Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of $C_{15}H_{11}ClN_2O_2$.

IDENTIFICATION

The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Diluent: Methanol and water (9:1)

Buffer: 8.5 g/L of monobasic potassium phosphate in water. Adjust with 1 N sodium hydroxide to a pH of 6.5.

Mobile phase: Methanol and *Buffer* (3:2)

Standard solution: 0.1 mg/mL of USP Oxazepam RS in *Diluent*

Sample solution: 0.1 mg/mL of oxazepam in *Diluent*, from the contents of NLT 20 Capsules. [Note—Sonicate for 15 min and shake for 15 min. Pass through a filter of 0.45-µm pore size.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 232 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection size: 20 µL

Run time: At least 1.7 times the retention time of oxazepam

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{15}H_{11}ClN_2O_2$ in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Oxazepam RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of oxazepam in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 1000 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard stock solution: 0.1 mg/mL of USP Oxazepam RS in methanol

[Note—Prepare NMT 30 min before use.]

Standard solution: 0.01 mg/mL of USP Oxazepam RS in *Medium* from the *Standard stock solution*. [Note—Keep it at about 6° for the *Analysis*. This solution is stable for 72 h if kept refrigerated.]

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Keep it at about 6° for the *Analysis*.

Mobile phase: Methanol, water, and glacial acetic acid (60:40:1)

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 232 nm

Column: 4-mm × 15-cm; packing L7

Flow rate: 2 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5 for the oxazepam peak

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Tolerances: NLT 75% (Q) of the labeled amount of $C_{15}H_{11}ClN_2O_2$ is dissolved.

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

Organic Impurities

- **Procedure**

Diluent, Buffer, and **Mobile phase:** Proceed as directed in the *Assay*.

Standard solution: 2 µg/mL of USP Oxazepam RS in *Diluent*

Sample solution: 0.2 mg/mL of oxazepam in *Diluent*, from the contents of NLT 20 Capsules. [Note—Sonicate for 15 min and shake for 15 min. Pass through a filter of 0.45-µm pore size.]

Chromatographic system: Proceed as directed in the *Assay*.

Run time: 3.5 times the retention time of oxazepam

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each individual impurity from the *Sample solution*

r_S = peak response of oxazepam from the *Standard solution*

C_S = concentration of USP Oxazepam RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of oxazepam in the *Sample solution* (µg/mL)

Acceptance criteria

Individual impurities: See *Impurity Table 1*. [Note—Disregard peaks less than 0.05%.]

Total impurities: NMT 0.5%, not including 2-amino 5-chlorobenzophenone

Impurity Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Oxazepam	1.0	—
2-Amino 5-chlorobenzophenone	2.7	0.5
Any individual unspecified degradation product	—	0.1

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩
  USP Oxazepam RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
OXAZEPAM CAPSULES	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(6)

Current DocID: GUID-A04E5644-17C6-472E-BB9A-6A1276BF78DC_1_en-US

DOI: https://doi.org/10.31003/USPNF_M59200_01_01

DOI ref: n8qgz