Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Dec-2016
Document Type: USP Monographs
DocId: GUID-A050141A-749C-41D2-B474-72F03D18BFDE_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1377_01_01
DOI Ref: edn8u

Alprazolam Compounded Oral Suspension

DEFINITION

Alprazolam Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of alprazolam ($C_{17}H_{13}ClN_4$).

Prepare Alprazolam Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Alprazolam	100 mg
Vehicle: a 1:1 mixture of Vehicle for Oral Solution (regular or sugar-free), *NF*, and Vehicle for Oral Suspension, *NF*, a sufficient quantity to make	100 mL

Comminute tablets in a suitable mortar to a fine powder, or add *Alprazolam* powder. Add about 20 mL of the *Vehicle*, and mix to a uniform paste. Add the *Vehicle* in small portions almost to volume, and mix thoroughly after each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Buffer: 0.04 M sodium acetate solution. Adjust with glacial acetic acid to a pH of 2.4.

Mobile phase: Methanol, acetonitrile, and *Buffer* (45:8:47)

Standard solution: 20 µg/mL of USP Alprazolam RS in *Mobile phase*

Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at −70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix with a vortex mixer for 30 s. Dilute a suitable volume of the Oral Suspension in *Mobile phase* to obtain a nominal concentration of 20 µg/mL.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 0.6 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time of alprazolam is about 10 min.]

Suitability requirements

Relative standard deviation: NMT 1.4% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of alprazolam ($C_{17}H_{13}ClN_4$) in the portion of Oral Suspension 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 Alprazolam RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH ⟨791⟩:** 4.0–5.0

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature, or in a refrigerator.
- **Beyond-Use Date:** NMT 60 days after the day on which it was compounded when stored at controlled room temperature or in a refrigerator
- **Labeling:** Label it to state that it is to be well-shaken before use, and to state the *Beyond-Use Date*.
- **USP Reference Standards** ⟨11⟩
  USP Alprazolam RS

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

Topic/Question	Contact	Expert Committee
ALPRAZOLAM COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(5)

Current DocID: GUID-A050141A-749C-41D2-B474-72F03D18BFDE_1_en-US

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