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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), <i>NF</i> , and Vehicle for Oral Suspension, <i>NF</i> , 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:

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