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Diazoxide Oral Suspension

DEFINITION

Diazoxide Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of diazoxide ($C_8H_7ClN_2O_2S$).

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Sample solution: Equivalent to 1 mg/mL of diazoxide prepared as follows. Place a portion of Oral Suspension equivalent to 50 mg of diazoxide in a 50-mL volumetric flask. Add 30 mL of 0.1 N sodium hydroxide, shake for 30 min, and dilute with 0.1 N sodium hydroxide to volume.

Developing solvent system: Methanol, ethyl acetate, and ammonium hydroxide (40:170:30)

Acceptance criteria: Meets the requirements

• B. The retention time of the *Sample solution* corresponds to that of the *Standard solution*, both relative to the *Internal standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Mobile phase: Methanol, glacial acetic acid, and 0.01 M sodium 1-pentanesulfonate (20:1:80)

Diluent: Methanol and water (1:4)

Internal standard solution: 2 mg/mL of hydrochlorothiazide in methanol

Standard stock solution: 1 mg/mL of [USP Diazoxide RS](#) in methanol

Standard solution: 50 µg/mL of [USP Diazoxide RS](#) and 40 µg/mL of hydrochlorothiazide prepared as follows. Transfer 5.0 mL of the *Standard stock solution* to a 100-mL volumetric flask, add 2.0 mL of *Internal standard solution*, and dilute with *Diluent* to volume.

Sample stock solution: Transfer an amount equivalent to about 100 mg of diazoxide from freshly mixed Oral Suspension to a 50-mL centrifuge tube. Add 2 mL of water and 35 mL of methanol, shake for 15 min, and centrifuge for 5 min. Transfer the supernatant to a 200-mL volumetric flask. Repeat the extraction process two times, beginning with the addition of 2 mL of water, combine the extracts in the 200-mL volumetric flask, and dilute with methanol to volume.

Sample solution: Transfer 10.0 mL of the *Sample stock solution* to a 100-mL volumetric flask, add 2.0 mL of *Internal standard solution*, and dilute with *Diluent* to volume.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L11

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times of hydrochlorothiazide and diazoxide are about 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 5 between the diazoxide and hydrochlorothiazide peaks

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of diazoxide ($C_8H_7ClN_2O_2S$) in the portion of Oral Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of diazoxide to the internal standard from the *Sample solution*

R_S = peak response ratio of diazoxide to the internal standard from the *Standard solution*

C_S = concentration of [USP Diazoxide RS](#) in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meets the requirements for Oral Suspension packaged in single-unit containers
- [DELIVERABLE VOLUME \(698\)](#): Meets the requirements for Oral Suspension packaged in multiple-unit containers

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Diazoxide RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DIAZOXIDE ORAL SUSPENSION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

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