

Diltiazem Hydrochloride Compounded Oral Suspension

DEFINITION
Diltiazem Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of diltiazem hydrochloride ($C_{22}H_{26}N_2O_4S \cdot HCl$).

Prepare Diltiazem Hydrochloride Compounded Oral Suspension 12 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Diltiazem Hydrochloride	1.2 g
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

If using tablets, comminute the tablets to a fine powder in a suitable mortar, or add *Diltiazem Hydrochloride* powder to the mortar. Add 10 mL of *Vehicle*, and mix to a uniform paste. Add *Vehicle* to the mortar 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 enough *Vehicle* to bring to final volume.

ASSAY

- PROCEDURE**

Solution A: 1.16 mg/mL of *d*-10-camphorsulfonic acid in 0.1 M sodium acetate. Adjust with 0.1 N sodium hydroxide to a pH of 6.2.

Mobile phase: Acetonitrile, methanol, and *Solution A* (50:25:25). Filter and degas.

Standard solution: 120 µg/mL of [USP Diltiazem Hydrochloride 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. Pipet 1.0 mL of the sample into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

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

Mode: LC

Detector: UV 240 nm

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

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for diltiazem is about 9.6 min.]

Suitability requirements

Relative standard deviation: NMT 1.3% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of diltiazem hydrochloride ($C_{22}H_{26}N_2O_4S \cdot HCl$) in the portion of Oral Suspension taken:

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 Diltiazem Hydrochloride RS](#) in the *Standard solution* (µg/mL)

C_u = nominal concentration of diltiazem hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 3.7–4.7

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 date 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, and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS** (11).
[USP Diltiazem Hydrochloride RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

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