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Verapamil Hydrochloride Compounded Oral Solution

DEFINITION

Verapamil Hydrochloride Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of verapamil hydrochloride ($C_{27}H_{38}N_2O_4 \cdot HCl$).

Prepare Verapamil Hydrochloride Compounded Oral Solution 50 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Verapamil Hydrochloride powder	5 g
Vehicle for Oral Solution (regular or sugar-free), *NF*, a sufficient quantity to make	100 mL

Add *Verapamil Hydrochloride powder* and about 40 mL of *Vehicle* to a mortar, and mix. 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 the preparation to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 0.01 N sodium acetate solution containing 33 mL/L of acetic acid

Mobile phase: Acetonitrile, 2-aminoheptane, and *Solution A* (50:0.5:50). Filter, and degas.

Standard solution: 500 µg/mL of USP Verapamil Hydrochloride RS in *Mobile phase*

Sample solution: Agitate containers of Oral Solution 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 on 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 278 nm

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

Flow rate: 0.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for verapamil hydrochloride is about 4.8 min.]

Suitability requirements

Relative standard deviation: NMT 0.7% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of verapamil hydrochloride ($C_{27}H_{38}N_2O_4 \cdot HCl$) in the portion of Oral Solution 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 Verapamil Hydrochloride RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.8–4.8

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 to indicate the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Verapamil Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
VERAPAMIL HYDROCHLORIDE COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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