

Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2019
 Document Type: USP Monographs
 DocId: GUID-E31580DD-183C-4B6C-8575-825504A42D38_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M88095_04_01
 DOI Ref: a0h11

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Verapamil Hydrochloride Injection

DEFINITION

Verapamil Hydrochloride Injection is a sterile solution of Verapamil Hydrochloride in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of verapamil hydrochloride ($C_{27}H_{38}N_2O_4 \cdot HCl$).

IDENTIFICATION

Change to read:

- **A.** ▲The UV spectrum of the major peak of the *Diluted sample solution* corresponds to that of the *Diluted standard solution*, as obtained in the Assay.▲ (USP 1-May-2019)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** ~~IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Chloride:~~ Meets the requirements

ASSAY

Change to read:

• PROCEDURE

Solution A: 0.015 N [sodium acetate](#) solution containing 33 mL of [glacial acetic acid](#) per liter

Mobile phase: [Acetonitrile](#), *Solution A*, and [2-aminoheptane](#) (30:70:0.5)

System suitability solution: 1.9 mg/mL of [USP Verapamil Hydrochloride RS](#) and 1.5 mg/mL of [USP Verapamil Related Compound B RS](#) in *Mobile phase*

Standard solution: 2.5 mg/mL of [USP Verapamil Hydrochloride RS](#) in *Mobile phase*

▲**Diluted standard solution:** 0.5 mg/mL of [USP Verapamil Hydrochloride RS](#) from the *Standard solution* in *Mobile phase*▲ (USP 1-May-2019)

Sample solution: Nominally 2.5 mg/mL of verapamil hydrochloride from a volume of Injection in *Mobile phase*

▲**Diluted sample solution:** Nominally 0.5 mg/mL of verapamil hydrochloride from the *Sample solution* in *Mobile phase*▲ (USP 1-May-2019)

Chromatographic system

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

Mode: LC

Detector: UV 278 nm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2019)

Column: 4.6-mm × ▲ (USP 1-May-2019) 15-cm; ▲5-μm▲ (USP 1-May-2019) packing [L1](#)

Flow rate: 0.9 mL/min

Injection volume: 10 μL

Run time: NLT 4 times the retention time of verapamil

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for verapamil related compound B and verapamil are about 0.88 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between verapamil related compound B and verapamil, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution*, ▲*Diluted standard solution*,▲ (USP 1-May-2019) *Sample solution*, ▲and *Diluted sample solution*

[NOTE—The *Diluted standard solution* and *Diluted sample solution* are used for *Identification A*.]▲ (USP 1-May-2019)

Calculate the percentage of the labeled amount of verapamil hydrochloride ($C_{27}H_{38}N_2O_4 \cdot HCl$) in the volume of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of verapamil from the *Sample solution*

r_S = peak response of verapamil from the *Standard solution*

C_S = concentration of [USP Verapamil Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Solution A, Mobile phase, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 2.5 mg/mL of [USP Verapamil Hydrochloride RS](#), and 7.5 µg/mL each of [USP Verapamil Related Compound A RS](#), [USP Verapamil Related Compound E RS](#), and [USP Verapamil Related Compound F RS](#) in *Mobile phase*

System suitability

▲**Samples:** *System suitability solution* and *Standard solution*

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between verapamil related compound B and verapamil, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Signal-to-noise ratio: NLT 15 for verapamil related compound F, *Standard solution* ▲ (USP 1-May-2019)

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each ▲specified degradation product ▲ (USP 1-May-2019) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of ▲verapamil related compound A, E, or F ▲ (USP 1-May-2019) from the *Sample solution*

r_S = peak response of ▲verapamil related compound A, E, or F ▲ (USP 1-May-2019) from the *Standard solution*

C_S = concentration of ▲[USP Verapamil Related Compound A RS](#), [USP Verapamil Related Compound E RS](#), or [USP Verapamil Related Compound F RS](#) ▲ (USP 1-May-2019) in the *Standard solution* (mg/mL) ▲ (USP 1-May-2019)

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

▲Calculate the percentage of any unspecified degradation product in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of any unspecified degradation product from the *Sample solution*

r_S = peak response of verapamil from the *Standard solution*

C_S = concentration of [USP Verapamil Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of verapamil hydrochloride in the *Sample solution* (mg/mL) ▲ (USP 1-May-2019)

Acceptance criteria: See [Table 1](#).

▲Table 1