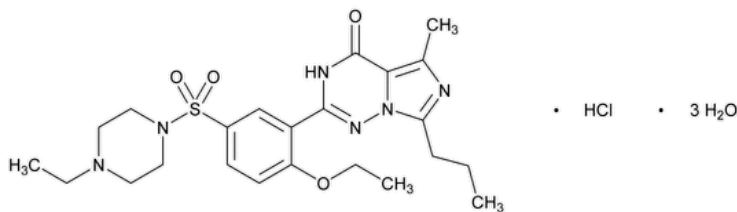


Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-470EE0C5-F2F4-466B-A528-FD6B0B192CE0_2_en-US
DOI: https://doi.org/10.31003/USPNF_M1032_02_01
DOI Ref: s8z9o

© 2025 USPC
Do not distribute

Vardenafil Hydrochloride



$C_{23}H_{32}N_6O_4S \cdot HCl \cdot 3H_2O$ 579.11
Piperazine, 1-[[3-(1,4-dihydro-5-methyl-4-oxo-7-propylimidazo[5,1-f][1,2,4]triazin-2-yl)-4-ethoxyphenyl]sulfonyl]-4-ethyl-, monohydrochloride, trihydrate-;
2-[2-Ethoxy-5-(4-ethyl-piperazine-1-sulfonyl)-phenyl]-5-methyl-7-propyl-3H-imidazo[5,1-f][1,2,4]triazin-4-one, hydrochloride, trihydrate CAS RN®: 330808-88-3; UNII: 5M8S2CU0TS.
Anhydrous 525.06 CAS RN®: 224785-91-5; UNII: IF61NL91H3.

DEFINITION
Vardenafil Hydrochloride contains NLT 98.0% and NMT 102.0% of vardenafil hydrochloride ($C_{23}H_{32}N_6O_4S \cdot HCl$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **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, Chloride\(191\)](#): Meets the requirements

ASSAY

• **PROCEDURE**

Protect all solutions containing vardenafil from light.
Buffer: Dissolve 1.3 g of monobasic potassium phosphate and 0.7 g of dibasic sodium phosphate dihydrate in 1 L of water.
Mobile phase: See [Table 1](#). Return to original conditions, and re-equilibrate the system.

Table 1

Time (min)	Buffer (%)	Acetonitrile (%)
0	80	20
2	80	20
22	25	75
27	25	75

System suitability solution: 0.5 mg/mL of [USP Vardenafil System Suitability RS](#) prepared as follows. Transfer an appropriate quantity of the Reference Standard to a volumetric flask. Add 20% of the flask volume of acetonitrile and dilute with *Buffer* to volume.
Standard solution: 0.15 mg/mL of [USP Vardenafil Hydrochloride RS](#) prepared as follows. Transfer an appropriate quantity of [USP Vardenafil Hydrochloride RS](#) to a volumetric flask. Add 20% of the flask volume of acetonitrile and dilute with *Buffer* to volume.

Sample solution: 0.15 mg/mL of Vardenafil Hydrochloride prepared as follows. Transfer an appropriate quantity of Vardenafil Hydrochloride to a volumetric flask. Add 20% of the flask volume of acetonitrile and dilute with *Buffer* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 242 nm

Column: 3-mm × 25-cm; 5-μm packing L1

Column temperature: 45°

Flow rate: 0.5 mL/min

Injection volume: 10 μL

System suitability

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

Suitability requirements

Resolution: NLT 5.0 between vardenafil and 7-methyl vardenafil, *System suitability solution*

Relative standard deviation: NMT 0.85%, *Standard solution*

Tailing factor: 0.8–1.5, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of vardenafil hydrochloride ($C_{23}H_{32}N_6O_4S \cdot HCl$) in the portion of Vardenafil Hydrochloride taken:

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

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

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

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

C_U = concentration of Vardenafil Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES**

Protect all solutions containing vardenafil from light.

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

Diluent: Acetonitrile and *Buffer* (20:80)

Standard stock solution: 0.5 mg/mL of [USP Vardenafil Hydrochloride RS](#) prepared as follows. Transfer an appropriate quantity of the Reference Standard to a volumetric flask. Add 20% of the flask volume of acetonitrile and dilute with *Buffer* to volume.

Standard solution: 0.5 μg/mL of [USP Vardenafil Hydrochloride RS](#) in *Diluent* from the *Standard stock solution*

Sample solution: 0.5 mg/mL of Vardenafil Hydrochloride prepared as follows. Transfer an appropriate quantity of Vardenafil Hydrochloride to a volumetric flask. Add 20% of the flask volume of acetonitrile and dilute with *Buffer* to volume.

System suitability

[NOTE—See [Table 2](#) for the relative retention times.]

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

Suitability requirements

Resolution: NLT 5.0 between vardenafil and 7-methyl vardenafil, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Vardenafil Hydrochloride taken:

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

r_U = peak response of each impurity from the *Sample solution*

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