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Venlafaxine Tablets

DEFINITION

Venlafaxine Tablets contain an amount of venlafaxine hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of venlafaxine free base ($C_{17}H_{27}NO_2$).

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Buffer: 3.4 g of [potassium dihydrogen phosphate](#) in 700 mL of [water](#). Add 5 mL of [triethylamine](#), and adjust with [phosphoric acid](#) to a pH of 3.0.

Diluent: Methanol and [0.1 N hydrochloric acid](#) (80:20)

Mobile phase: Acetonitrile and *Buffer* (30:70)

Standard solution: 0.3 mg/mL of venlafaxine free base from a suitable quantity of [USP Venlafaxine Hydrochloride RS](#) in *Diluent*

Sample solution: Nominally 0.3 mg/mL of venlafaxine (from NLT 20 finely powdered Tablets) in *Diluent*. Sonicate for 30 min. Centrifuge and pass a portion of the supernatant through a suitable membrane filter of 0.45- μ m pore size. [NOTE—A centrifuge speed of 4000 rpm for 10 min may be suitable.]

Chromatographic system

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

Mode: LC

Detector: UV 275 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Flow rate: 1.0 mL/min

Injection volume: 10 μ L

Run time: 5 times the retention time of the venlafaxine peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of venlafaxine free base ($C_{17}H_{27}NO_2$) in the portion of Tablets 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 venlafaxine free base in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0% of the labeled amount of venlafaxine free base ($C_{17}H_{27}NO_2$)

PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#)
Medium: [Water, deaerated](#); 900 mL
Apparatus 2: 50 rpm
Time: 30 min
Standard stock solution: 0.84 mg/mL of venlafaxine free base from a suitable quantity of [USP Venlafaxine Hydrochloride RS](#) in [methanol](#)
Standard solution: (L/1000) mg/mL of venlafaxine free base in *Medium*, where L is the label claim in mg/Tablet, from the *Standard stock solution*
Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.
Detector: UV 275 nm
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of venlafaxine free base (C₁₇H₂₇NO₂) dissolved:

Result = (A_U/A_S) × (C_S/L) × V × 100

- A_U = absorbance of the *Sample solution*
A_S = absorbance of the *Standard solution*
C_S = concentration of venlafaxine free base in the *Standard solution* (mg/mL)
L = label claim (mg/Tablet)
V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of venlafaxine free base (C₁₇H₂₇NO₂) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

- ORGANIC IMPURITIES**
Buffer: Prepare as directed in the Assay.
Solution A: Acetonitrile and *Buffer* (20:80)
Solution B: Acetonitrile and *Buffer* (35:65)
Diluent: Acetonitrile and *Buffer* (30:70)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
25	0	100
30	0	100
32	100	0
45	100	0

- System suitability solution:** 0.0018 mg/mL of [USP Venlafaxine Related Compound A RS](#) and 0.6 mg/mL of [USP Venlafaxine Hydrochloride RS](#) in *Diluent*
Standard stock solution: 0.6 mg/mL of [USP Venlafaxine Hydrochloride RS](#) in *Diluent*
Standard solution: 0.0018 mg/mL of [USP Venlafaxine Hydrochloride RS](#) in *Diluent* from the *Standard stock solution*
Sample solution: Nominally 0.6 mg/mL of venlafaxine (from NLT 20 finely powdered Tablets) in *Diluent*. Centrifuge and pass a portion through a suitable membrane filter of 0.45-µm pore size. [NOTE—Sonicate, if necessary. A centrifuge speed of 4000 rpm for 10 min may be