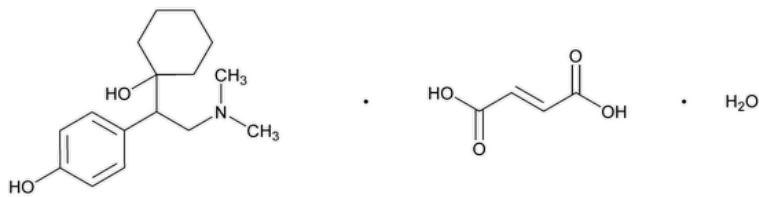


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Desvenlafaxine Fumarate



$C_{16}H_{25}NO_2 \cdot C_4H_4O_4 \cdot H_2O$ 397.46
 $C_{16}H_{25}NO_2 \cdot C_4H_4O_4$ 379.45
trans-Butenedioic acid, compound with 4-[2-(dimethylamino)-1-(1-hydroxycyclohexyl)ethyl]phenol (1:1), monohydrate;
1-[2-(Dimethylamino)-1-(4-hydroxyphenyl)ethyl]cyclohexanol hydrogen (*E*)-but-2-enedioate monohydrate CAS RN®: 313471-75-9; UNII: R5JHD7L72A.
Anhydrous CAS RN®: 93414-04-1; UNII: ATX24E9M6L.

DEFINITION

Desvenlafaxine Fumarate contains NLT 98.0% and NMT 102.0% of desvenlafaxine fumarate ($C_{16}H_{25}NO_2 \cdot C_4H_4O_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** **SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A (ERR 1-Oct-2020)
- **B.** The retention times of the desvenlafaxine and fumaric acid peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: To each liter of [water](#), add 1 mL of [triethylamine](#) and adjust with [phosphoric acid](#) to a pH of 3.0.
Solution A: [Acetonitrile](#) and *Buffer* (10:90)
Solution B: [Acetonitrile](#) and *Buffer* (60:40)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
4	70	30
4.1	10	90
4.5	10	90
4.6	80	20
7	80	20

Diluent: *Solution A* and *Solution B* (50:50)

Standard solution: 0.05 mg/mL of [USP Desvenlafaxine Fumarate RS](#) in *Diluent*. Sonication may be used to promote dissolution.

Sample solution: 0.05 mg/mL of Desvenlafaxine Fumarate in *Diluent*. Sonication may be used to promote dissolution.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 2.1-mm × 15-cm; 1.7-µm packing [L1](#)

Column temperature: 55°

Flow rate: 0.3 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for fumaric acid and desvenlafaxine are 0.48 and 1.0, respectively.]

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of desvenlafaxine fumarate ($C_{16}H_{25}NO_2 \cdot C_4H_4O_4$) in the portion of Desvenlafaxine Fumarate taken:

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

- r_U = peak response of desvenlafaxine from the *Sample solution*
- r_S = peak response of desvenlafaxine from the *Standard solution*
- C_S = concentration of [USP Desvenlafaxine Fumarate RS](#) in the *Standard solution* (mg/mL)
- C_U = concentration of Desvenlafaxine Fumarate 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**

Buffer, Solution A, Solution B, Diluent, and Chromatographic system: Proceed as directed in the Assay.

Mobile phase: See [Table 2](#).

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	95	5
5	90	10
15	55	45
27	50	50
27.1	95	5
30	95	5

System suitability solution: 1 mg/mL of [USP Desvenlafaxine Fumarate RS](#) and 0.0015 mg/mL of [USP Desvenlafaxine Related Compound B RS](#) in *Diluent*

Sensitivity solution: 0.5 µg/mL of [USP Desvenlafaxine Fumarate RS](#), equivalent to 0.3 µg/mL of desvenlafaxine, in *Diluent*