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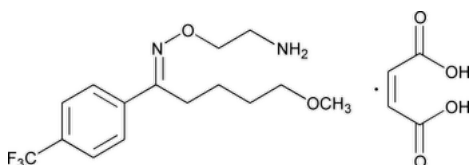
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Fluvoxamine Maleate

 $C_{15}H_{21}F_3N_2O_2 \cdot C_4H_4O_4$

434.41

1-Pentanone, 5-methoxy-1-[4-(trifluoromethyl)phenyl]-, O-(2-aminoethyl)oxime, (E)-, (Z)-2-butenedioate (1:1);

(E)-5-Methoxy-4'-(trifluoromethyl)valerophenone O-(2-aminoethyl)oxime, maleate (1:1) CAS RN®: 61718-82-9; UNII: 5LGN83G74V.

DEFINITION

Fluvoxamine Maleate contains NLT 98.0% and NMT 102.0% of fluvoxamine maleate ($C_{15}H_{21}F_3N_2O_2 \cdot C_4H_4O_4$), calculated on the dried 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.

ASSAY

PROCEDURE

Solution A: 8 g/L of [sodium 1-pentanesulfonate](#) and 1.1 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.00 ± 0.05 .

Mobile phase: Acetonitrile and *Solution A* (38:62)

System suitability solution: Transfer 6 mg of Fluvoxamine Maleate to a 50-mL volumetric flask. Heat the sample at 120° for 10 min. Cool to room temperature, and add 3.0 mL of [0.1 N hydrochloric acid](#). Heat the solution in a water bath for 10 min. Cool to room temperature, add 50 mg of Fluvoxamine Maleate, and dissolve in 25 mL of *Mobile phase*. Dilute with *Mobile phase* to volume.

Standard solution: 0.05 mg/mL of [USP Fluvoxamine Maleate RS](#) in *Mobile phase*

Sample solution: 0.05 mg/mL of Fluvoxamine Maleate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 234 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L7](#)

Column temperature: 40°

Flow rate: 1.7 mL/min

Injection volume: 20 μ L

Run time: NLT 2.5 times the retention of fluvoxamine

System suitability

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

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

Suitability requirements

Resolution: NLT 3.0 between the Z-isomer and fluvoxamine maleate; NLT 5.0 between succinyl fluvoxamine and the Z-isomer, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fluvoxamine maleate ($C_{15}H_{21}F_3N_2O_2 \cdot C_4H_4O_4$) in the portion of Fluvoxamine Maleate taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

C_U = concentration of Fluvoxamine Maleate in the *Sample solution* (mg/mL)

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

IMPURITIES

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

• ORGANIC IMPURITIES

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

Identification solution: 0.35 mg/mL of [maleic acid](#) in *Mobile phase*

Sample solution: 1 mg/mL of Fluvoxamine Maleate in *Mobile phase*

Chromatographic system: Proceed as directed in the Assay except for the *Run time*.

Run time: NLT 6 times the retention of fluvoxamine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Fluvoxamine Maleate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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

r_S = peak area of fluvoxamine from the *Standard solution*

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

C_U = concentration of Fluvoxamine Maleate in the *Sample solution* (mg/mL)

F = relative response factor for each impurity (see [Table 1](#))

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

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Maleic acid ^a	0.19	—	—
Succinyl fluvoxamine ^b	0.50	1.0	0.3
Aminoethyl fluvoxamine ^c	0.67	0.71	0.2
Z-isomer ^d	0.79	1.0	0.5
Fluvoxamine	1.0	—	—
Aminoethyl desmethoxy fluvoxamine ^e	1.2	1.0	0.2
Dealkyl benzyl fluvoxamine ^f	1.7	1.0	0.2
Desmethoxy fluvoxamine ^g	2.0	1.0	0.2
Fluvoxamine oxime ^h	3.5	1.7	0.2