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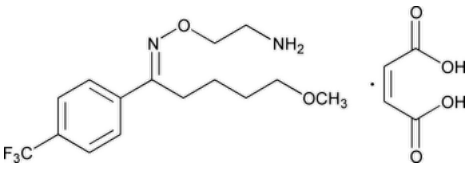
# Fluvoxamine Maleate



$C_{15}H_{21}F_3N_2O_2 \cdot C_4H_4O_4$ 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 × 25-cm; 5-µm packing L7

**Column temperature:** 40°

**Flow rate:** 1.7 mL/min

**Injection volume:** 20 µL

**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 |

| Name | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) |
|---|---|---|---|
| Valerophenone analog[i] | 4.2 | 3.3 | 0.2 |
| Any individual unspecified impurity | — | 1.0 | 0.1 |
| Total impurities | — | — | 1.5 |

[a] This is the counterion. It is not to be reported or included in the total impurities.

[b] (*E*)-5-Methoxy-1-[4-(trifluoromethyl)phenyl]-1-pentanone *O*-[2-[(2-succinyl)amino]ethyl]oxime.

[c] (*E*)-5-Methoxy-1-[4-(trifluoromethyl)phenyl]pentan-1-one *O*-{2-[(2-aminoethyl)amino]ethyl}oxime.

[d] (*Z*)-5-Methoxy-1-[4-(trifluoromethyl)phenyl]pentan-1-one *O*-(2-aminoethyl)oxime.

[e] (*E*)-1-[4-(Trifluoromethyl)phenyl]pentan-1-one *O*-{2-[(2-aminoethyl)amino]ethyl}oxime.

[f] (*E*)-2-Phenyl-1-[4-(trifluoromethyl)phenyl]ethan-1-one *O*-(2-aminoethyl)oxime.

[g] (*E*)-1-[4-(Trifluoromethyl)phenyl]pentan-1-one *O*-(2-aminoethyl)oxime.

[h] (*E*)-5-Methoxy-1-[4-(trifluoromethyl)phenyl]pentan-1-one oxime.

[i] 5-Methoxy-1-(4-(trifluoromethyl)phenyl)pentan-1-one.

## SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

**Analysis:** Dry under vacuum at 80° for 2 h.

**Acceptance criteria:** NMT 0.5%

## ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers. Store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Fluvoxamine Maleate RS

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| FLUVOXAMINE MALEATE | Documentary Standards Support | SM42020 Small Molecules 4 |

**Chromatographic Database Information:** Chromatographic Database

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