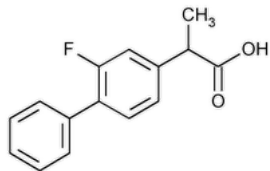


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Flurbiprofen

Change to read:



$C_{15}H_{13}FO_2$ ▲244.27 ▲ (USP 1-Dec-2023)
[1,1'-Biphenyl]-4-acetic acid, 2-fluoro- α -methyl-, ($\pm$);
▲(RS)-2-(2-Fluoro-[1,1'-biphenyl]-4-yl)propanoic acid ▲ (USP 1-Dec-2023) CAS RN®: 5104-49-4; UNII: 5GRO578KLP.

Change to read:

DEFINITION

Flurbiprofen contains ▲NLT 98.0% and NMT 102.0% ▲ (USP 1-Dec-2023) of flurbiprofen ($C_{15}H_{13}FO_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): ▲197A or ▲ (USP 1-Dec-2023) 197K

Delete the following:

- ▲ • **B.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy](#) ▲ (USP 1-Dec-2023)

Add the following:

- ▲ • **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-Dec-2023)

ASSAY

Change to read:

• **PROCEDURE**

▲ **Solution A:** Dissolve 1.26 g of [ammonium formate](#) in 1000 mL of [water](#). Adjust with [formic acid](#) to a pH of 3.0.

Solution B: [Acetonitrile](#) and [methanol](#) (50:50)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	40	60
3	40	60
30	30	70
35	30	70
36	40	60
40	40	60

Diluent: [Acetonitrile](#) and [water](#) (45:55)

Standard solution: 0.2 mg/mL of [USP Flurbiprofen RS](#) in *Diluent*

Sample solution: 0.2 mg/mL of Flurbiprofen in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of flurbiprofen ($C_{15}H_{13}FO_2$) in the portion of Flurbiprofen taken:

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

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

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

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

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

Acceptance criteria: 98.0%–102.0% on the dried basis ▲ (USP 1-Dec-2023)

IMPURITIES

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

Change to read:

- **ORGANIC IMPURITIES**

▲ **Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system:** Proceed as directed in the Assay.

Sensitivity solution: 0.5 μg/mL of [USP Flurbiprofen RS](#) in *Diluent*

System suitability solution: 1.0 mg/mL of [USP Flurbiprofen RS](#) and 5 μg/mL of [USP Flurbiprofen Related Compound A RS](#) in *Diluent*

Standard solution: 1.0 μg/mL each of [USP Flurbiprofen RS](#) and [USP Flurbiprofen Related Compound A RS](#) in *Diluent*

Sample solution: 1.0 mg/mL of Flurbiprofen in *Diluent*

System suitability

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

[NOTE—The relative retention times for flurbiprofen related compound A and flurbiprofen are 0.95 and 1.0, respectively. These relative retention times are provided as information that could aid in peak assignment.]

Suitability requirements

Resolution: NLT 1.5 between flurbiprofen related compound A and flurbiprofen, *System suitability solution*

Relative standard deviation: NMT 5.0% for flurbiprofen related compound A and flurbiprofen, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of flurbiprofen related compound A in the portion of Flurbiprofen taken:

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

r_U = peak response of flurbiprofen related compound A from the *Sample solution*

r_S = peak response of flurbiprofen related compound A from the *Standard solution*

C_S = concentration of [USP Flurbiprofen Related Compound A RS](#) in the *Standard solution* (mg/mL)

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

Calculate the percentage of any unspecified impurity in the portion of Flurbiprofen taken:

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