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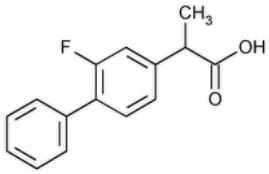
Flurbiprofen

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-, (±)-;
▲(*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:

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

r_U = peak response of any unspecified impurity 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: See *Table 2*. The reporting threshold is 0.05%.

Table 2

Name	Acceptance Criteria, NMT (%)
Flurbiprofen related compound A	0.5
Any unspecified impurity	0.10
Total impurities	1.0▲ (USP 1-Dec-2023)

SPECIFIC TESTS

- **Melting Range or Temperature ⟨741⟩:** 114°–117°
- **Loss on Drying ⟨731⟩**

  Analysis: Dry in vacuum at 60° to constant weight.

  Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.

Change to read:

- **USP Reference Standards ⟨11⟩**

  USP Flurbiprofen RS

  USP Flurbiprofen Related Compound A RS

  ▲2-(Biphenyl-4-yl)propanoic acid.▲ (USP 1-Dec-2023)

  $C_{15}H_{14}O_2$ 226.28

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

Topic/Question	Contact	Expert Committee
FLURBIPROFEN	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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