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Flurbiprofen Tablets

DEFINITION
Flurbiprofen Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of flurbiprofen ($C_{15}H_{13}FO_2$).

IDENTIFICATION

• **A. Infrared Absorption**

Sample: Place 100 mg of flurbiprofen from a number of Tablets in a flask. Add 10 mL of 0.1 N hydrochloric acid, and sonicate until the Tablets disintegrate. Extract with two 15-mL portions of ether, and combine the ether extracts in a flask containing 1 g of anhydrous sodium sulfate. Decant the ether, and evaporate to dryness.

Acceptance criteria: The IR absorption spectrum of a mineral oil dispersion of the residue exhibits maxima only at the same wavelengths as those of a similar solution of USP Flurbiprofen RS.

• **B.** The retention time of the major peak for flurbiprofen in the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

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 stock solution: Nominally 1.0 mg/mL of flurbiprofen in *Diluent* prepared as follows. Transfer a quantity of finely crushed Tablets (NLT 10), nominally equivalent to 25 mg of flurbiprofen, to a 25-mL volumetric flask. Add 15 mL of *Diluent* and sonicate. [Note—A sonication time of 30 min may be suitable.]. Dilute with *Diluent* to volume. Centrifuge and use the clear supernatant.

Sample solution: Nominally 0.2 mg/mL of flurbiprofen from the *Sample stock solution* in *Diluent*. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

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 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of flurbiprofen ($C_{15}H_{13}FO_2$) in the portion of Tablets 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 = nominal concentration of flurbiprofen in the *Sample solution* (mg/mL)

▲ (USP 1-Dec-2023)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Medium stock solution: 122.5 g/L of monobasic potassium phosphate and 25 g/L of sodium hydroxide in water

Medium: Dilute 166.5 mL of the *Medium stock solution* with water to 3000 mL. If necessary, adjust with 5 N sodium hydroxide or with phosphoric acid to a pH of 7.20 ± 0.05; 900 mL.

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: A known concentration of USP Flurbiprofen RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Suitably dilute with *Medium* to obtain a concentration similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at 247 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of flurbiprofen ($C_{15}H_{13}FO_2$) dissolved:

$$\text{▲Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Tablet)

▲ (USP 1-Dec-2023)

Tolerances: NLT 75% (Q) of the labeled amount of flurbiprofen ($C_{15}H_{13}FO_2$) is dissolved.

Change to read:

• **Uniformity of Dosage Units** ▲▲(USP 1-Dec 2023) ⟨905⟩**:** ▲Meet the requirements▲ (USP 1-Dec-2023)

IMPURITIES

Change to read:

• **Organic Impurities**

Mobile: Acetonitrile, glacial acetic acid, and water (35:5:60)

Diluent: Acetonitrile and water (45:55)

Standard solution A: 0.004 mg/mL of USP Flurbiprofen RS in *Diluent*

Standard solution B: 0.01 mg/mL of USP Flurbiprofen Related Compound A RS in *Diluent*

▲**Sensitivity solution:** 0.002 mg/mL of USP Flurbiprofen RS in *Diluent*▲ (USP 1-Dec-2023)

Sample solution: Nominally 2 mg/mL of flurbiprofen prepared as follows. Weigh, and finely powder Tablets (NLT 20). Dissolve 500 mg of flurbiprofen from a portion of powdered Tablets in 50 mL of water, add 200 mL of acetonitrile, centrifuge, and use the supernatant.

System suitability solution: 0.01 mg/mL each of USP Flurbiprofen RS and USP Flurbiprofen Related Compound A RS▲ in *Diluent*.▲ (USP 1-Dec-2023)

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution A*, ▲*Sensitivity solution*,▲ (USP 1-Dec-2023) and *System suitability solution*

▲[NOTE—The relative retention times for flurbiprofen related compound A and flurbiprofen are 0.87 and 1.0, respectively. These relative retention times are provided as information that could aid in peak assignment.]▲ (USP 1-DEC-2023)

Suitability requirements

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

Relative standard deviation: NMT 5% ▲▲ (USP 1-Dec-2023) , *Standard solution A*

▲**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*▲ (USP 1-Dec-2023)

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Calculate the percentage of flurbiprofen related compound A in the portion of Tablets 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 *Standard solution B*

C_S = concentration of USP Flurbiprofen Related Compound A RS in *Standard solution B* (mg/mL)

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

Calculate the percentage of any ▲▲ (USP 1-Dec-2023) unspecified impurity in the portion of Tablets taken:

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

r_U = peak response for any unspecified impurity from the *Sample solution*

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

C_S = concentration of USP Flurbiprofen RS in *Standard solution A* (mg/mL)

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

Acceptance criteria: See *Table 2*. ▲The reporting threshold is 0.1%.▲ (USP 1-Dec-2023)

Table 2

▲Name	Acceptance Criteria, NMT (%)
Flurbiprofen related compound A	0.5
Any unspecified impurity	0.2
Total impurities	1.0▲ (USP 1-Dec-2023)

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in well-closed containers. ▲Protect from light. Store at controlled room temperature.▲ (USP 1-Dec-2023)

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 TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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