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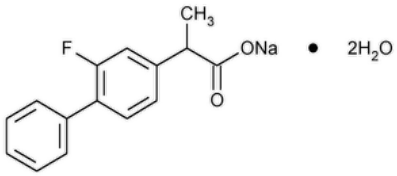
Flurbiprofen Sodium



$C_{15}H_{12}FNaO_2 \cdot 2H_2O$ 302.27
[1,1'-Biphenyl]-4-acetic acid, 2-fluoro-α-methyl, sodium salt dihydrate, (±)-.
Sodium (±)-2-(2-fluoro-4-biphenylyl)propionate dihydrate.
Anhydrous 266.25

» Flurbiprofen Sodium contains not less than 97.0 percent and not more than 103.0 percent of $C_{15}H_{12}FNaO_2 \cdot 2H_2O$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Flurbiprofen RS
USP Flurbiprofen Sodium RS
USP Flurbiprofen Related Compound A RS
2-(4-Biphenylyl)propionic acid.
$C_{15}H_{14}O_2$ 226.28

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197M*▲ (CN 1-May-2020) —

Test specimen: previously dried.

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020)

Solution: 10 µg per mL.

Medium: pH 6.0 buffer consisting of 2.42 g of monobasic sodium phosphate and 0.66 g of dibasic sodium phosphate dissolved in water to make 1000 mL.

Absorptivities at 246 nm, calculated on the dried basis, do not differ by more than 3.0%.

C: The residue obtained by igniting it meets the requirements of the tests for *Sodium* ⟨191⟩.

Specific rotation ⟨781S⟩: between −0.45° and +0.45°.

Test solution: 50 mg per mL, in methanol.

Loss on drying ⟨731⟩—Dry about 0.3 g of it in vacuum at a pressure not exceeding 1 mm of mercury over phosphorus pentoxide in a suitable drying tube at 60° for 18 hours: it loses not less than 11.3% and not more than 12.5% of its weight.

Limit of flurbiprofen related compound A—

Diluent, *Mobile phase*, and *System suitability preparation*—Proceed as directed in the *Assay.*

Standard solution—Use *Standard flurbiprofen related compound A preparation*, prepared as directed in the *Assay.*

Test solution—Use the *Assay preparation*.

Chromatographic system—Proceed as directed in the *Assay*, except to chromatograph the *Standard solution* instead of the *Standard preparation.*

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the percentage of flurbiprofen related compound A in the portion of Flurbiprofen Sodium taken by the formula:

$$200(C/W)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Flurbiprofen Related Compound A RS in the *Standard solution; W* is the weight, in mg, of the portion of Flurbiprofen Sodium taken to prepare the *Test solution;* and r_U and r_S are the peak areas for flurbiprofen related compound A obtained from the *Test solution* and the *Standard solution*, respectively: not more than 1.5% is found.

Assay—

Diluent—Mix 500 mL of methanol and 250 mL of water.

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile, water, and glacial acetic acid (50:49:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard flurbiprofen related compound A preparation—Dissolve an accurately weighed quantity of USP Flurbiprofen Related Compound A RS in methanol to obtain a stock solution having a known concentration of about 150 µg per mL. Transfer 1.0 mL of this solution to a 200-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Flurbiprofen RS in methanol to obtain a stock solution having a known concentration of about 1 mg per mL. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix.

System suitability preparation—Transfer 5 mL of the stock solution used to prepare the *Standard preparation* and 2 mL of the stock solution used to prepare the *Standard flurbiprofen related compound A preparation* to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Assay preparation—Transfer about 100 mg of Flurbiprofen Sodium, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with methanol to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.0-mm × 25-cm column that contains 10-µm packing L7. The flow rate is about 2 mL per minute. Chromatograph the *System suitability preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between flurbiprofen related compound A and flurbiprofen is not less than 1.0. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2.5; and the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the percentage of $C_{15}H_{12}FNaO_2 \cdot 2H_2O$ in the portion of Flurbiprofen Sodium taken by the formula:

$$200(302.27/244.27)(C/W)(r_U/r_S)$$

in which 302.27 and 244.27 are the molecular weights of flurbiprofen sodium dihydrate and anhydrous flurbiprofen, respectively; C is the concentration, in µg per mL, of USP Flurbiprofen RS in the *Standard preparation; W* is the weight, in mg, of the portion of Flurbiprofen Sodium taken to prepare the *Assay preparation;* and r_U and r_S are the flurbiprofen peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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