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Flurbiprofen Sodium Ophthalmic Solution

» Flurbiprofen Sodium Ophthalmic Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of flurbiprofen sodium ($C_{15}H_{12}FNaO_2 \cdot 2H_2O$).

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11).—

[USP Flurbiprofen RS](#)
[USP Flurbiprofen Related Compound A RS](#)
2-(4-Biphenyl)propionic acid.
 $C_{15}H_{14}O_2$ 226.28

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

pH (791): between 6.0 and 7.0.

ANTIMICROBIAL EFFECTIVENESS (51): meets the requirements.

STERILITY TESTS (71).—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

Assay—

Diluent, Mobile phase, Standard flurbiprofen related compound A preparation, Standard preparation, and System suitability preparation—Proceed as directed in the *Assay* under [Flurbiprofen Sodium](#).

Assay preparation—Use the undiluted Ophthalmic Solution.

Chromatographic system—Proceed as directed in the *Assay* under [Flurbiprofen Sodium](#), using a 4.0-mm × 5-cm guard column that contains 5-μm packing L1.

Procedure—Separately inject equal volumes (about 15 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 quantity of flurbiprofen sodium ($C_{15}H_{12}FNaO_2 \cdot 2H_2O$) in each mL of the Ophthalmic Solution taken by the formula:

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

in which 302.27 and 244.27 are the molecular weights of flurbiprofen sodium dihydrate and anhydrous flurbiprofen, respectively; C is the concentration, in mg per mL, of [USP Flurbiprofen RS](#) in the *Standard preparation*; and r_U and r_S are the 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 OPHTHALMIC SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

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