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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  $\times$  5-cm guard column that contains 5- $\mu$ m packing L1.

**Procedure**—Separately inject equal volumes (about 15  $\mu$ L) 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	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

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