Bromfenac Sodium Ophthalmic Solution

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Bromfenac Sodium Ophthamic Solution is an aqueous ophthalmic preparation.

It contains not less than 90.0% and not more than 110.0% of the labeled amount of Bromfenac Sodium Hydrate ($C_{15}H_{11}BrNNaO_3.1½H_2O$: 383.17).

Method of preparation Prepare as directed under Ophthalmic Liquids and Solutions, with Bromfenac Sodium Hydrate.

Description Bromfenac Sodium Ophthalmic Solution occurs as a clear and yellow liquid.

Identification To a volume of Bromfenac Sodium Ophthalmic Solution, equivalent to 1 mg of Bromfenac Sodium Hydrate, add a solution of sodium hydrogen carbonate (21 in 2500) to make 50 mL, and determine the absorption spectrum of this solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits maxima between 266 nm and 270 nm, and between 377 nm and 381 nm.

pH Being specified separately when the drug is granted approval based on the Law.

Purity Related substances—Being specified separately when the drug is granted approval based on the Law.

Foreign insoluble matter *<6.11>* It meets the requirement.

Insoluble particulate matter *<6.08>* It meets the requirement.

Sterility *<4.06>* Perform the test according to the Membrane filtration method: it meets the requirement.

Assay Pipet a volume of Bromfenac Sodium Ophthalmic Solution, equivalent to 2 mg of Bromfenac Sodium Hydrate, add the mobile phase to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 20 mg of Bromfenac Sodium RS (separately determine the water *<2.48>* in the same manner as Bromfenac Sodium Hydrate), and dissolve in the mobile phase to make exactly 20 mL. Pipet 2 mL of this solution, add the mobile phase to make exactly 20 mL, and use this solution as the standard solution. Perform the test with 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography *<2.01>* according to the following conditions, and determine the peak areas, A_T and A_S, of bromfenac in each solution.

Amount (mg) of bromfenac sodium hydrate ($C_{15}H_{11}BrNNaO_3.1½H_2O$)

$= M_S \times A_T / A_S \times 1/10 \times 1.076$

M_S: Amount (mg) of Bromfenac Sodium RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 266 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40℃.

Mobile phase: Dissolve 1.98 g of diammonium hydrogen phosphate in 750 mL of water, adjust to pH 7.3 with phosphoric acid, and add 250 mL of acetonitrile.

Flow rate: Adjust so that the retention time of bromfenac is about 18 minutes.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of bromfenac are not less than 13,000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of bromfenac is not more than 1.0%.

Containers and storage Containers—Tight containers.

Add the following to 9.01 Reference Standard (1):

Bromfenac Sodium RS