Bromfenac Sodium Ophthalmic Solution

Bromfenac Sodium Ophthalmic 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 \((C_{13}H_{11}BrNaO_3\cdot\frac{1}{2}H_2O: 383.17)\).

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 206 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 \(\mu L\) 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.

Add the following to 9.01 Reference Standard (1):

Bromfenac Sodium RS