



CATALYST FOR SUCCESS

► ANALYSIS OF ALENDRONIC ACID IN PHARMACEUTICAL FORMULATIONS

Alendronic acid or Alendronate Sodium is a bisphosphonate drug that inhibits osteoclast-mediated bone resorption. Biphosphates work by binding to the bone and preventing calcium from being removed by osteoclasts. This drug is used to prevent and treat osteoporosis as well as several other bone diseases. Alendronate Sodium is sold as tablets or solutions, alone or in combination with Vitamin D.

Since Alendronic acid has no chromophore, post-column derivatization is employed to produce a fluorescence derivative.

This abstract describes selective and sensitive analytical method for the analysis of Alendronic Acid in pharmaceutical tablets. Simple sample preparation and fast analysis time allow for using this method in high throughput environments.

METHOD

Analytical Conditions

Column: Anion-exchange,
4.1x150 mm,
catalog number 1441150

Temperature: 45 °C

Flow Rate: 1.0 mL/min

Mobile Phase: Sodium Nitrate, 50 mM,
pH 7.8 / Methanol (60:40)

Post-Column Conditions

Post-Column System: Pinnacle PCX

Heated Reactor Volume: 0.5 mL

Reactor Temperature: 70 °C

Reagent: OPA (300 mg), Thiofluor (2g),
30 % Brij 35 (3 mL) in 950 mL of OD104

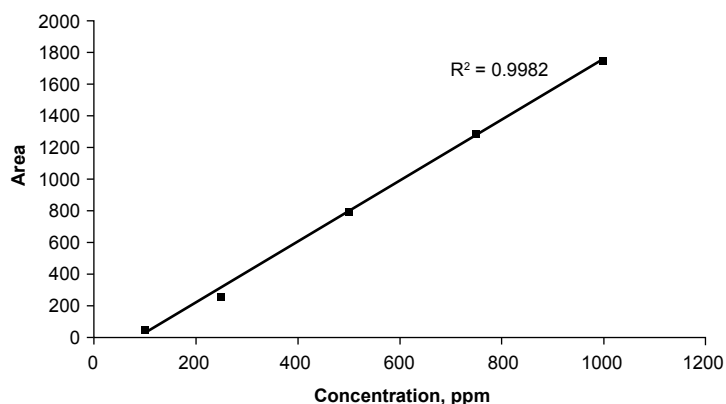
Reagent Flow Rate: 0.5 mL/min

Detection: FLD

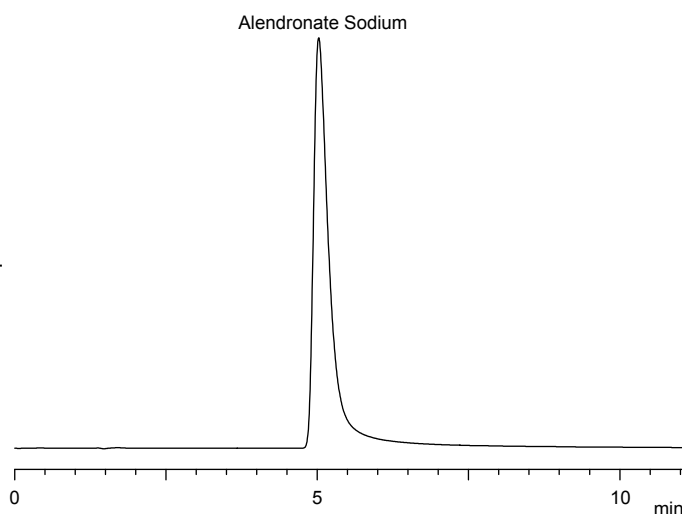
λ_{ex} : 330 nm, λ_{em} : 465 nm

Sample Preparation

Crush 1 tablet and mix with water. Use enough water to get Alendronate Sodium concentration between 300 and 1000 µg/mL. Heat the solution using a water bath to 65 °C and stir for 30 min. Filter liquid portion through 0.45 µm filter. Put filtrate in HPLC autosampler vial and inject 10 µL



Calibration curve for analytical range 100-1000 ppm



Chromatogram of Fosavance® tablet
(Alendronate sodium 70 mg, Vitamin D 2800 IU)