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Validation of RP HPLC method for determination of ibandronate sodium in pharmaceutical dosage form

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Ibandronate sodium [(1-hydroxy-3-(methyl pentyl amino) propylidene bisphosphonic acid monosodium monohydrate)] is the sodium salt of ibandronic acid, a synthetic nitrogen-containing bisphosphonate drug. This new, third generation bisphosphonate is used in treatment of bone diseases like Paget's disease, malignant hypercalcemia and postmenopausal osteoporosis. A simple, accurate and sensitive liquid chromatographic method has been developed for the assay of ibandronate sodium in tablet dosage form. The separation was achieved on C18 (250x4.6 mm), 5 µm chromatographic column. Mobile phase was mixture of 1 mL ortho-phosphoric acid, 50 mL CH3CN, 0.96 g Na pentansulfonate and 0.1 g Na EDTA in 1000 mL H2O. Column temperature was 40 °C, mobile phase flow rate 1.0 mL/min and detection wavelength 195 nm. The method was validated according to ICH Q2 (R1) requirements. It was proved that method is specific for determination of ibandronate sodium. Linearity was confirmed with calculated r value (r=0.9996). Accuracy was tested at three concentrations levels (80%, 100% and 120%) and confirmed by obtained Recovery values (98.40–99.89%). Precision was tested at two levels: intra-assay precision and intermediate precision. Calculated relative standard deviations were 0.29% and 0.83%, respectively. Small variations of mobile phase composition (proportion of organic solvent, concentration of ion pair reagent) and column temperature did not affect qualitative and quantitative system responses significantly, which proved method's robustness. Applicability of the method was confirmed by analysis of commercially available tablets.

Biography

Ivković Branka has completed PhD from University of Belgrade, Faculty of Pharmacy, Department of Pharmaceutical Chemistry.

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