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Radioanalytical chromatography techniques for newly developed radiopharmaceutical: ^{99m}Tc-ibandronate sodium



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Statement of the Problem: Bisphosphonates (BPs) are chemically stable pyrophosphate analogues, and used to treat pathological conditions associated with bone mass loss. Radiolabeled BPs, which used as bone-seeking radiopharmaceuticals for imaging or therapy hold an important place in nuclear medicine, radiopharmaceuticals are radioactive drugs containing a pharmaceutical compound and a suitable radionuclide. While biologically active molecule or drug acts as a carrier and determines localization, the radionuclide permits external detection. FDA approved radiopharmaceuticals as drugs and it is mandatory to satisfy the guidelines for quality control tests which include the radiochemical, radionuclidic and chemical purity as well as checks for pharmaceutical concerns. In the past 10 years, separation and quality control methods such as radioactive thin layer chromatography (RTLC), high performance liquid chromatography (HPLC) and electrophoresis have widely used in radiopharmaceutical studies. In radiopharmaceutical research laboratories, it is important that the labeled compound is obtained in high yields. Radiolabeled agents may contain impurities like unlabeled radionuclide used for radiolabeling, with degradation products formed during oxidation or reduction of radionuclide and secondary complexes which should be formed during radiolabeling reaction. Thus, the estimation of impurities in the radiolabeled compounds is significant.

Methodology & Theoretical Orientation: In this work, a new radiolabeled bisphosphonate complex, ^{99m}Tc-ibandronate sodium (^{99m}Tc-IBD), was developed and quality control studies were achieved by using RTLC and paper electrophoresis methods. For this purpose, different stationary and mobile phases were used and ideal TLC system conditions were developed. Furthermore, paper electrophoresis studies were performed for each formulation. ^{99m}Tc-IBD complex was prepared by using different reducing agent concentrations. Some parameters like effect of antioxidant agent and pH on labeling yield were also investigated. For quality control methods, Whatman 1 MM and 3 MM papers, silica gel (SG) coated fiber sheets and instant thin layer chromatography SG (ITLC-SG) plates were used as stationary phase and acetone, physiologic solution, methylethylketon, acetonitrile/water/ trifluoroacetic acid, butanol/ethanol/water solutions were used as mobile phases.

Findings: A new RTLC method conditions for ^{99m}Tc-IBD complex providing high radiochemical yield (over 95%) were developed with ITLC-SG plates as stationary phase and acetone and acetonitrile/water/trifluoroacetic acid solutions as mobile phases.

Conclusion & Significance: In conclusion, newly developed chromatography method for ^{99m}Tc-IBD can be useful for further studies.

Biography

Meliha Ekinci has obtained her Master's degree in Radiopharmacy at Ege University, Turkey in 2015. She is currently a PhD student and also a Research Assistant at Radiopharmacy Department, Ege University, Turkey. She has published 12 research papers and review articles and 26 conference presentations. Her main research interest focuses on radiolabeling and evaluating newly developed radiopharmaceuticals for diagnosis of different cancer types, especially breast cancer, and novel drug delivery systems (nanoparticles, microemulsions, etc.). She has completed four scientific research projects, and is currently working on three projects about New Radiopharmaceuticals. She is a Member of professional societies like European Federation of Pharmaceutical Sciences (EUFEPS) and Society of Radiopharmaceutical Sciences (SRS) and some local societies like Turkish Pharmacists Association 3rd Region Izmir Pharmacist Chamber. She has 35 citations up to now.

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