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Additional Method for the Purification of Lanthanide-Labeled Peptide Compounds Pre-Purified by Weak Cation Exchange Cartridge

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Abstract : Aim: Purification of the final product, which is the last step in the synthesis of lanthanide-labeled peptide compounds, can be accomplished by different methods. Among these methods, the two most commonly used methods are C18 solid phase extraction (SPE) and weak cation exchanger cartridge elution. SPE C18 solid phase extraction method yields high purity final product, while elution from the weak cation exchanger cartridge is pH dependent and ineffective in removing colloidal impurities. The aim of this work is to develop an additional purification method for the lanthanide-labeled peptide compound in cases where the desired radionuclidic and radiochemical purity of the final product can not be achieved because of pH problem or colloidal impurity. Material and Methods: For colloidal impurity formation, 3 mL of water for injection (WFI) was added to 30 mCi of 177LuCl3 solution and allowed to stand for 1 day. 177Lu-DOTATATE was synthesized using EZAG ML-EAZY module (10 mCi/mL). After synthesis, the final product was mixed with the colloidal impurity solution (total volume:13 mL, total activity: 40 mCi). The resulting mixture was trapped in SPE-C18 cartridge. The cartridge was washed with 10 ml saline to remove impurities to the waste vial. The product trapped in the cartridge was eluted with 2 ml of 50% ethanol and collected to the final product vial via passing through a 0.22µm filter. The final product was diluted with 10 mL of saline. Radiochemical purity before and after purification was analysed by HPLC method. (column: ACE C18-100A. 3µm. 150 x 3.0mm, mobile phase: Water-Acetonitrile-Trifluoro acetic acid (75:25:1), flow rate: 0.6 mL/min). Results: UV and radioactivity detector results in HPLC analysis showed that colloidal impurities were completely removed from the 177Lu-DOTATATE/ colloidal impurity mixture by purification method. Conclusion: The improved purification method can be used as an additional method to remove impurities that may result from the lanthanide-peptide synthesis in which the weak cation exchange purification technique is used as the last step. The purification of the final product and the GMP compliance (the final aseptic filtration and the sterile disposable system components) are two major advantages.

Keywords : lanthanide, peptide, labeling, purification, radionuclide, radiopharmaceutical, synthesis
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