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FREEZE-DRIED KIT FOR QUICK AND EFFICIENT PREPARATION OF 188ReN-DEDC/LIPIODOL IN HOSPITAL RADIOPHARMACY

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Background: 188ReN-DEDC/lipiodol(DEDC –diethyldithiocarbamate) is a clinically established agent for the therapy of unresectable hepatocellular carcinoma (HCC). Original two-vial method for the preparation of 188ReN-DEDC/lipiodol involved compulsory addition of stipulated amount of glacial acetic acid (GAA), which was cumbersome in a busy radiopharmacy. Moreover, an error in glacial acetic acid volume had significant impact on overall yield of 188ReN-DEDC complex. Herein, we present a two-vial kit for quick, efficient and glacial acetic acid free preparation of 188ReN-DEDC/lipiodol.

Methodology:
Sterile two-vial freeze-dried kits, vial 1 containing N-methyl-S-methyl dithiocarbazate (DTCz) (2 mg), SnCl2⊠2H2O (0.8 mg), oxalic acid (28 mg), sodium ascorbate (10 mg) and vial 2 containing DEDC (100 mg), were prepared in a clean room facility. In the first step, 188ReN-core was prepared by adding freshly eluted sodium perrhenate (1-5 mL, ˜3700 MBq), obtained from a tungsten-188/rhenium-188 generator, into kit vial 1. Vial 1 was gently shaken to dissolve the contents and incubated at room temperature for 5 min. In the second step, kit vial 2 was reconstituted with 2 mL of physiological saline. About 1 mL of the reconstituted solution was transferred into kit vial 1. Subsequently, vial 1 was sequentially incubated at room temperature for 15 min, at 65⊠C for 5 min and then cooled to room temperature. To extract 188ReN-DEDC complex, lipiodol (2-3 mL) was added into kit vial 1 and the contents are mixed for 10 min. Clear separation of two layers was achieved by centrifugation of vial 1 at 1600g for another 10 min. Subsequently, lipiodol layer containing 188ReN-DEDC was carefully separated for further use. The quality control of 188ReN-DEDC/lipiodol was carried out by TLC in dichloromethane. Developed strip was analyzed on a TLC scanner and radiochemical purity (RCP) was determined from peak area measurements.

Results and discussions:
The use of GAA reported in the original method of preparation of 188ReN-DEDC complex was avoided by including oxalic acid/sodium ascorbate combination to provide an acidic environment conducive for 188ReN formation. This modification also brought significant reduction in time required for patient dose preparation. Presence of ascorbate provided an additional protection from possible radiolytic damage to 188ReN core as well as 188ReN-DEDC complex. Using kit vial 1, 188ReN-core could be consistently prepared in quantitative yield within 5 minutes. Upon addition of the constituents from kit vial 2 following the recommended procedure, 188ReN-DEDC complex could be prepared in >85% yield. It was observed that >99% of 188ReN-DEDC complex could be extracted into lipidol phase in the first attempt itself. Quality control of the lipiodol phase confirmed absence of perrhenate.

Conclusion: The two-vial freeze-dried kit presented here offer a quick and efficient way for the preparation of 188ReN-DEDC/lipiodol in a hospital radiopharmacy setup and allows the use of upto five ml of radioactive solution, making a step forward from the original method in terms of ease of patient dose preparation as well as effective utilization of the 188W-188Re generator.

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