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Development of ready-to-use 177Lu-PSMA-617 formulation for treatment of inoperable metastatic prostate cancer

Background:
Prostate cancer is the second most prevalent cancer worldwide. 177Lu-PSMA-617 has emerged as a useful therapeutic modality in the management of metastatic castration-resistant prostate cancer. The present work describes a ready-to-use 177Lu-PSMA-617 injectable formulation of the therapeutic radiopharmaceutical, produced using medium specific activity 177Lu (> 15 Ci/mg), and evaluated for its integrity and performance three days post its preparation.

Methods:
The radiolabeling procedure was optimised typically for 10.0 GBq dose; by heating 177LuCl3 (corresponding 0.1-0.2 mL; Sp. Act. > 555 GBq/mg) with commercially available (CMR, Russia) or indigenously synthesized PSMA-617 peptide (2.0-2.5 equiv.) in sodium acetate buffer (pH 5.0; 0.6 mL) containing sodium ascorbate (2 mg) at 95℃ for 15-20 min. The crude radiolabeled product was then passed through Sep-Pak C18 purification assembly to yield the final product in ethanol which was diluted with 0.1 M sodium acetate buffer containing 2% sodium ascorbate to reduce the final ethanolic content below 10%. The diluted radiopharmaceutical was then sterilized by membrane filtration and dispensed as a single patient dose (7.4 GBq) with activity calibration of 2 days. The preparation was then stored at -20℃ and shipped under dry ice conditions.

Result:
Peptide to metal ratio and pH of the reaction mixture are key factors responsible to achieve high radiolabeling yields (> 95%) and hence recoveries of the radiolabeled product post C18 purification. Out of 15 batches, only one batch, recovery yield observed was less than 95%. The labeled product, at a radiochemical concentration of the range of 740 ±74 MBq/mL (0.1 M sodium acetate buffer with 2% sodium ascorbate) was found to stable for 9 days when stored at -20℃. Ten clinical studies carried in diseased patients with activities in the range of 5.55-7.40 GBq using ready-to-use formulation 1-3 days post its formulation, showed an affinity towards the lesions with symptomatic relief to the patients.

Conclusion:
A new 'ready-to-use'177Lu-PSMA-617 formulation has been developed and validated for its end-use up to three days post its formulation. Clinical effectiveness studies showed a positive response in a limited number of diseased patients.

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