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Título: Evaluation of quenchers in the stability of 177Lu-PSMA-I&T

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Introdução: The radiopharmaceutical 177Lu-PSMA-I&T has been extensively studied worldwide, primarily for the treatment of metastatic castration-resistant prostate cancer, due to its high affinity to prostate-specific membrane antigen (PSMA). Stability studies are fundamental to ensure the quality of the radiopharmaceutical, particularly for therapeutic agents labeled with β- emitting radionuclides as Lu-177, because radiolytic effects can compromise product integrity. In this context, some stabilizing agents (quenchers) may be utilized in the final formulation of 177Lu-PSMA-I&T. Evaluating the efficacy of each agent is an essential strategy to preserve the product quality and to determine the shelf-life.

Objetivos: The objective of this study was to evaluate the effect of different quenchers on the radiochemical purity percentage (% RCP) of 177Lu-PSMA-I&T produced with Lu-177 no-carrier-added (N.C.A.), aiming to determine the radiopharmaceutical stability.

Material e Métodos: Radiolabeling procedures used 48.1 GBq of N.C.A 177LuCl3 and 830–1110 ug of PSMA-I&T in 8 mL of sodium ascorbate buffer (pH 4.7), at 90 oC during 30 minutes. DTPA solution was introduced after the labeling, followed by the dose filling 0.74 GBq per vial, with a final volume of 4.5 mL, calibrated for 48 hours (2 days), using 3 different diluent quencher's solutions: NaCl 0.9 %, NaCl 0.9 % containing additional ascorbic acid and NaCl 0.9 % containing gentisic acid. Additionally, the effect of volume on stability was evaluated by diluting the preparation containing gentisic acid to 7.5 mL per dose.

The % RCP was determined by HPLC immediately, after 24 and 48 hours of radiolabeling, stored under -20+/- 5 oC. The results were compared by analyzing the influence of various quenchers and dilution volume on product stability.

Resultados:

Conclusão: The results demonstrated that the addition of quenchers contributed significantly to the stability of 177Lu-PSMA-I&T prepared with N.C.A. Lu-177. In comparative assessment, for a final dose volume of 4.5 mL, ascorbic acid showed better stabilizing potential. Overall, the formulation containing gentisic acid in a final volume of 7.5 mL provided the most effective maintenance of radiochemical purity, showing that dilution can also be used as a stabilizing factor for therapeutic radiopharmaceuticals.

Palavras-chave: *177Lu-PSMA-I&T; stability; quenchers*

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