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^{177}Lu-PSMA-617: Brazilian Experience

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Abstract

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Introduction: PSMA-617 radiolabeled with lutetium-177 has shown good results in compassionate studies around the world, and there is great interest in this kind of therapy in Brazil. The Nuclear and Research Institute (IPEN-CNEN) in São Paulo city, is a national radiopharmaceutical producer and the distribution of radiopharmaceuticals for therapy in a country of continental dimensions such as Brazil, becomes a challenge from the standpoint of guaranteeing the stability of the product. This work evaluated the scheduling of pilot batches for the production of ^{177}Lu-PSMA-617 and studied the effect of dilution and freezing on the stability of mono-doses of the product. **Materials and Methods:** Radiolabeling of PSMA-617 (ABX, Germany) with lutetium-177 (JSC, Russia) was performed in heating block at 90 °C for 30 minutes, 37 GBq (1 Ci), 500 µg of peptide and sodium ascorbate (0,5 M pH 4,7) as buffer. At the end of the radiolabel, 0,5 mL of DTPA solution (4 mg/mL pH 4,5) was added and the product was diluted with an appropriate volume of saline solution 0,9%. The final product was filtrated in 0.22 membrane and the doses were fractionated (7,4 GBq calibrated for 24 hours in approximately 2,4 mL) and conditioned in appropriate lead chambers inside a dry ice bucket for transport simulation. The radiochemical purity (RP) was evaluated in a stability study at, 24 and 48 hours by TLC and HPLC. The radionuclidic purity, sterility and bacterial endotoxins were also evaluated. **Results and discussion:** The radiopharmaceutical was stable after 48 hours (99.47% TLC and 99.39% HPLC), and was approved in radionuclidic, sterility and endotoxins assays. The vials fractionated in mono-doses calibrated for 24 hours showed high stability through freezing and dilution, which allowed the transportation to the Cancer Hospital of Barretos, distant 420 km from the production center in São Paulo. All these mono-doses were administrated to the patients after 24 hours of the production. Also, these results denote that is possible to scale up this production until 74 GBq and be used in a clinical trial that is being planned.

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Conclusions: These carried out experiments demonstrated that it is possible to produce ^{177}Lu-PSMA-617 for use in clinical trials in Brazil. Until now, four patients are under treatment (compassionate use). Also, these results demonstrate that it is still possible to increase production activity to 74 GBq, just like is normally done with ^{177}Lu-DOTATATE. **Acknowledgments:** Grant 2018/12965-4, São Paulo Research Foundation (FAPESP) and National Commission of Nuclear Energy.
