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RADIONUCLIDIC PURITY ASSESSMENT FOR RA-223 CHLORIDE RADIOPHARMACEUTICAL

F. Zagni[1], G. Cicoria[1], A. Corazza[3], C. Malizia[2], M. Marengo[1]
[1]Medical Physics Department, University Hospital "S.Orsola - Malpighi", Bologna, Italy
[2]PET Radiopharmacy Unit, University Hospital "S.Orsola - Malpighi", Bologna, Italy
[3]Postgraduate School in Medical Physics, University of Bologna, Italy

BACKGROUND-AIM

Ra-223 chloride (Xofigo®) is a novel radiopharmaceutical for the treatment of bone metastases of prostate cancer. Ra-223 is an alpha emitting radionuclide, obtained through a generator containing Ac-227/Th-227 (at equilibrium, half-life 21.8 years) which may contain traces of Ra-226 (1600 years) and Th-228 (1.9 years) due to the generator production process. In this work we assessed the presence of these and other long-lived contaminants using a HPGe gamma spectrometry system.

METHODS

The assessment was performed based on the analysis of gamma photons emission of Th-227, Bi-214/Pb210 and Pb-212/Bi-212, which were considered at secular equilibrium with parent nuclides Ac-227, Ra-226 and Th-228 respectively. 1 ml of the original radiopharmaceutical (1 MBq/ml) was taken and two measurements were performed, 2 and 6 months after the reference calibration time of the radiopharmaceutical. For both measurements an amount of the original Ra-223 and its daughters (at equilibrium) was still present and it was not considered for the evaluations.
Measurements were performed with a spectrometry system equipped with a HPGe detector and multi-channel analyzer based on digital electronics (Areva Canberra, distributed in Italy by TNE, Milan). The detector has a 30% relative efficiency and a resolution of 1.8 keV at 1332 keV. Calibration was performed in the 59-1836 keV range by means of a multi-radionuclide certified reference solution manufactured in a Standardization Laboratory (Areva CERCA LEA, France). The calibration process was performed according to the IEC 61452 standard (IEC, 1995), using the Genie 2000 software (Canberra, Meriden, USA). The calculations implemented in the software accounts for the propagation of the all the source of uncertainties, background subtraction and MDA estimation. The sample of Ra-223 was located in the same container corresponding to the geometry of calibration and acquired 1 hour for the first measurement (1100 cps, dead time 1.2%) and 4 hours for the second (5 cps, dead time 0.2%). All activities were calculated at the injection time of radiopharmaceutical.

RESULTS

In the first measurement (2 months after reference date) no contaminants were detected at all. Evaluated MDA values were 25 Bq for Th-227, 4 Bq for Ra-226 and 8 Bq for Th-228.
In the second measurement very few counts in the net peak areas of Th-227 characteristic peaks were detected, being the activity 1.1±0.1 Bq and the MDA 0.7 Bq. MDA for both Ra-226 and Th-228 was 0.4 Bq.

CONCLUSION

Th-227 was barely detectable with our spectrometer after 6 months from injection date, yielding to a purity of 99.99989%. Considring also the estimated MDA values for Ra-226 and Th-228 the purity value was 99.99977%. In conclusion, very high radionuclidic purity has been found for this radiopharmaceutical, leading to no unnecessary dose to patients and easing both the management of related wastes and authorization issues.