

عنوان مقاله:

Gallium-68 DOTATATE Production with Automated PET Radiopharmaceutical Synthesis System: A Three Year Experience

محل انتشار:

مجله پزشکی هسته ای و زیست شناسی آسیا اقیانوسیه, دوره 2, شماره 2 (سال: 1393)

تعداد صفحات اصل مقاله: 12

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خلاصه مقاله:

Objective(s): Gallium-68 (Ga-68) is an ideal research and hospital-based PET radioisotope. Currently, the main form of Ga-68 radiopharmaceutical that is being synthesised in-house is Ga-68 conjugated with DOTA based derivatives. The development of automated synthesis systems has increased the reliability, reproducibility and safety of radiopharmaceutical productions. Here we report on our three year, 500 syntheses experience with an automated system for Ga-68 DOTATATE. Methods: The automated synthesis system we use is divided into three parts of a) servomotor modules, b) single use sterile synthesis cassettes and, c) a computerized system that runs the modules. An audit trail is produced by the system as a requirement for GMP production. The required reagents and chemicals are made in-house. The Germanium breakthrough is determined on a weekly basis. Production yields for each synthesis are calculated to monitor the performance and efficiency of the synthesis. The quality of the final product is assessed after each synthesis by ITLC-SG and HPLC methods. Results: A total of 500 Ga-68 DOTATATE syntheses (> 800 patient doses) were performed between March 2011 and February 2014. The average generator yield was $81.3 \pm 0.2\%$ for 2011, $76.7 \pm 0.4\%$ for 2012 and $75.0 \pm 0.3\%$ for 2013. Ga-68 DOTATATE yields for 2011, 2012, and 2013 were $81.8 \pm 0.4\%$, $82.2 \pm 0.4\%$ and $87.9 \pm 0.4\%$, respectively. These exceed the manufacturer's expected value of approximately 70%. Germanium breakthrough averaged $8.6 \times 10^{-6}\%$ of total activity which is well below the recommended level of 0.001%. The average ITLC-measured radiochemical purity was above 98.5% and the average HPLC-measured radiochemical purity was above 99.5%. Although there were some system failures during synthesis, there were only eight occasions where the patient scans needed to be rescheduled. Conclusion: In our experience the automated synthesis system performs reliably with a relatively low incident of failures. Our system had a consistent and reliable Ga-68 DOTATATE output with high labelling efficiency and purity. There is minimal operator intervention and radiation exposure. The system is GMP-compliant and has low maintenance and acceptable running costs. This system together with the recommended $^{68}\text{Ge}/^{68}\text{Ga}$ generator is well suited for use in a hospital-based radiopharmacy

کلمات کلیدی:

DOTATATE, Automated synthesis systems, Gallium-68, Neuro-endocrine tumours, PET radiopharmaceuticals

