P266

Cyclotron-produced Tc-99m: Impurities, limits and QC methods

O. Lebeda[1], J. Ralis[1], A. Cepa[1], P. Hradilek[1], T. Vrba[2], A. Zyuzin[3], E. van Lier[3]; [1]Nuclear Physics Institute AS CR, Husinec-Rez, CZECH REPUBLIC, [2]Faculty of Nuclear Sciences and Physical Engineering CTU, Prague, CZECH REPUBLIC, [3]Advanced Cyclotron Systems Inc., Richmond, BC, CANADA.

Aim Search for technically feasible and economically sustainable alternative to reactor-produced ^{99}Mo/^{99m}Tc generators is natural answer to global shortage of ^{99}Mo supply and coming shut-down of key aging reactors. Direct ^{99m}Tc production on more than 700 installed medical cyclotrons all over the world is realistic, decentralized and flexible solution, since parameters like yield, radionuclidic, radiochemical and chemical purity meet the criteria for clinical use. We have, therefore, proposed and tested quality control methods for the product. Major difference between cyclotron- and generator-produced ^{99m}Tc pertechnetate is the radionuclidic impurities profile. Consequently, we calculated effective dose due to all radionuclidic impurities isotopic with ^{99m}Tc for chemical forms identical with ^{99m}Tc-based radiopharmaceuticals. Combined with prediction of radionuclidic composition of the cyclotron ^{99m}Tc for varying production parameters (target enrichment, beam energy, irradiation time and expiry), they provide guidance for setting each impurity limit. Materials and Methods Thick targets from highly enriched ^{100}Mo were irradiated on external 24MeV proton beam of the cyclotron U-120M at Nuclear Physics Institute, Rez, and processed using automated solid extraction chromatography. The obtained sodium (^{99m}Tc) pertechnetate in saline was analyzed using selected QC methods for radionuclidic, radiochemical and chemical purity, and used for reconstitution of several kits for production of the most widespread ^{99m}Tc radiopharmaceuticals. Content of ^{93m}Tc (43.5 min), ^{93}Tc (2.75 h), ^{94m}Tc (52 min), ^{94}Tc (4.883 h), ^{95m}Tc (61 d), ^{95}Tc (20.0 h), ^{96}Tc (4.28 d) and ^{97m}Tc (91 d) was predicted using recently published experimental data and verified using gamma spectrometry of both attenuated and decayed product. Residues of ^{99}Mo (65.95 h), ^{96}Nb (23.35 h) and ^{97}Nb (1.202 h) were assayed as well. Effective dose due to all the eight Tc radioisotopes present as pertechnetate, sestamibi, various forms of human serum albumin, medronate/oxidronate, betiatide, exametazime etc. was calculated using RADAR and ICRP data. Results and Conclusion Complete set of quality control methods for cyclotron-produced *Sodium (^{99m}Tc) pertechnetate* was proposed and implemented. All the batches showed steadily excellent radiochemical purity, good compatibility with commercially available kits, low content of aluminium and of radionuclidic impurities that agrees well with the predicted values. Having taken into account technical feasibility and acceptable increase of the patient's radiation burden, we proposed limits for each identified radionuclidic impurity. Limits for radiochemical and chemical purity can be adopted from the current monograph for generator-produced *Sodium (^{99m}Tc) pertechnetate* in EurPharm.

P12 — Sunday, October 19, 2014, 16:00 — 16:30, Poster Exhibition Area

Radiopharmaceuticals & Radiochemistry: Radiopharmacy & Radiometals

P267

Logarithmic decay as a model of the early time plasma concentration of [51]Cr-EDTA

S. N. Wanasundara[1], M. J. Wesolowski[1], R. C. Puetter[2], M. T. Burniston[3], E. Xirouchakis[3], I. G. Giamalis[3], P. S. Babyn[4], C. A. Wesolowski[1,5]; [1]University of Saskatchewan, Saskatoon, SK, CANADA, [2]Pixon Imaging, Inc., San Diego, CA, UNITED STATES, [3]The Royal Free London NHS Foundation Trust, London, UNITED KINGDOM, [4]Royal University Hospital, University of Saskatchewan, Saskatoon, SK, CANADA, [5]Memorial University of Newfoundland, St. John's, NL, CANADA.

Aim: Plasma clearance can be obtained using the total area under the plasma concentration curve (*AUC*) of a radiolabelled marker following a bolus intravenous injection of a glomerular filtration rate marker such as [51]Cr-EDTA. Clinically, *AUC* is often calculated by measuring concentration data after 120 min and using an exponential function to extrapolate the earlier concentration data. However, exponential functions have been found to model early concentration data poorly. The aim of this study is to find a better two-parameter function to model early plasma concentration data. **Methods:** In this study, exponential, C(t) = a exp(-b t) and logarithmic, C(t) = a – b ln t, functions were tested for fidelity of back-extrapolating plasma concentrations of [51]Cr-EDTA to sample-times before 120 min where C(t) is the concentration as a function of time t. Thirteen sets of concentration-time data were obtained from a previous clinical study with early data in which 3 to 11 blood samples were drawn between 5 min (n = 12) or 30 min (n =1) and 180-(n = 12) or 360-(n = 1) min after bolus injection. To test the goodness of early plasma concentration back-extrapolation, the two parameters of each test function were first obtained from solutions at 120 min and the next adjacent time-sample, at either 180 min (n = 12) or 360 min (n = 1). Subsequently, the predicted, back-extrapolated (before 120 min), concentrations from each of two functions were compared with the corresponding measured concentration early time-samples. **Results:** The average of the root mean square relative errors for all 13 cases, back-extrapolated sample concentrations before 120 min for logarithmic functions was 11.9%, less than half of the 24.4% exponential function error. Exponential functions consistently underestimated the concentration values of the earliest available samples (sign scores = +0/-13 and Wilcoxon p = 0.0002). The concentrations of the first time-samples were insignificantly different from the logarithmic function values at those times, Wilcoxon p = 0.45. Logarithmic functions did not trend toward either over- or under-estimation of measured concentrations; sign scores +7/-6. **Conclusion:** Early plasma concentrations of our [51]Cr-EDTA data exhibited logarithmic decay in time, and significantly not exponential decay. The results strongly suggest the use of logarithmic functions for interpolation of time-samples before 120 min for performing numerical integration of concentration to calculate *AUC*s.

P268

Computerized Management and Traceability System for Hospital Radiopharmacies

J. Gómez Perales; Andalusian Health Service (SAS), Cadiz, SPAIN.

Objective: The aim of this projet was to develop a software for comprehensive management and traceability for hospital radiopharmacies. Method: The computer application was developed in Microsoft VBA (Visual Basic for Applications) programming language, and with linked and interrelated tables of Microsoft Access. Results: We have developed a software (Radiolab) with 12 modules. The orders module to manage the issuing and receiving of orders (radioactive, cold kits and consumables). The stock module gives information at any time about the stock of radionuclides and cold kits. The generator module is used for the management of elutions of Tc-99m generators and the withdrawal of the Tc-99m generators from the radiopharmacy. The labelling module is used to record kits labelling, as well as in vitro cells labelling (leukocytes, red blood cells and platelets). The control module is used to register the stability and linearity controls of activity meter, radiochemical purity controls, cleaning procedures, microbiological controls, temperature controls and radiochromatograph controls. The dosage module is used to manage the dose dispensing of radiopharmaceuticals. The waste module gives information at any time about the activities of the radioactive waste for each radionuclide in real time. The tracking module allows traceability reports issued by patient name, radiopharmaceutical reference, radiotracer batch, generator batch and kit batch. The protocols module allows the management of standard operating procedures of radiopharmacy. The incidences module serves for monitoring incidences of the radiopharmacy. The maintenance module enables to backup the database, restoring the database from its backup, updating the radiopharmaceuticals catalogue, entering the user data and the staff of the radiopharmacy, compacting the database and setting for net working. In addition, the software has an agenda and a radioactive units converter. Conclusion: The software Radiolab, which is available on the Internet, is a useful tool for the comprehensive management and traceability of hospital radiopharmacies.