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QUALITY CONTROL SYSTEM FOR SHORT-LIVED RADIOPHARMACEUTICALS.

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Although short-lived radiopharmaceuticals labeled with C-11(half-life: 20 min.), N-13(10 min.), etc. have been used in research facilities with a cyclotron, it is often difficult to carry out the quality control before clinical uses, due to their short half-lives.

A new system was developed to shorten the time required for quality control, which enabled to measure the radiochemical purity, chemical purity, radionuclidic purity, specific activity, etc. of the product at a same time. The system consists of multi-purpose pulse-height-analyzer equipped with ADC(14 bits, 200 MHz) and VFC(10 Kcps/V), isolation amplifier and detectors(NaI, Ge, UV, TCD, etc.). Signals from several detectors can be fed to the pulse-height analyzer through ADC or VFC simultaneously. The characteristics of the system are as follows: 1) outputs from different detectors are scaled on a same time axis, 2) dwell time is programmable, 3) several chromatograms are obtained with γ -ray spectrum.

Using the system, quality control for $^{13}\text{N}\text{H}_3$, $^{11}\text{C}\text{-Ro15-1788}$ and $^{11}\text{C}\text{-MMBA}$ could be carried out within 3 minutes. This means that quality control prior to an administration is possible without any practical drop of the product quality, since it takes about 5 minutes from the delivery to the administration.

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^{18}F FLUORIDE PRODUCTION SYSTEM USING ENRICHED ^{18}O -WATER AS A TARGET. R.Iwata, T.Ido, M.Monma, F.Brady, T.Takahashi and A.Ujiie. Tohoku University, CYRIC and School of Medicine, Sendai.

A reproducible and efficient production of ^{18}F with enriched ^{18}O -water has been studied for its use in synthesis of ^{18}F -radiopharmaceuticals by nucleophilic substitution reactions. 1.5~2.5 mL of 20 % enriched ^{18}O -water were irradiated by 18 MeV protons with up to 20 μA currents in a Ti target vessel. Production yields of ^{18}F with a static or flow target using a low dead volume circulation pump were measured. Effects of current (5~20 μA), irradiation time (0.5~2 hr.), target thickness (3~5 mm), and target cooling on the yield were also investigated.

With a static target, a sudden decrease in production yield beyond 10 μA was observed, and the yield was only 30 % at 15~20 μA . On the other hand, a gradual decrease in the yield with a flow target was observed with increasing a current. The ^{18}F yield was 70 % (170 mCi) with a 5 mm target thickness and silver backing window at a 20 μA and 1 hour irradiation. It was found that the target water was significantly decreased by radiolytic decomposition with a flow target, depending on a current and irradiation time and this resulted in the yield decrease with over 2 hour irradiations. However, the yield was improved by recovering the decomposed water on Pd and returning it to the target.

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AN AUTOMATED SYNTHESIS SYSTEM OF F-18 FDG WITH ACETHYLHYPO[F-18]FLUORITE IN CLINICAL USE. Y. Miyake, Y. Ichiya, Y. Kuwabara, Z. Ayabe and A. Yoshimura.* Faculty of Medicine, Kyushu University and Radioisotope Center Kyushu University*, Fukuoka

It is well known that electrophilic addition using F-18 acethylhypofluorite (AcOF) has provided a better radiochemical yield and shorter than that using F-18 F_2 . Therefore, this approach is one of the most suitable method for the preparation of F-18 FDG in its clinical use. We have developed an automated synthesis system of F-18 FDG with F-18 AcOF in clinical use.

The synthetic procedure consist of four processes as follows: (1) F-18 AcOF generated in gas phase from sodium acetate trihydrate, (2) reaction of 3,4,6-tri-O-acetyl-D-glucal in fluorotrichloromethane at -78°C , (3) hydrolysis with 1N HCl, (4) purification of F-18 FDG by passing the hydrolysate through an ion-retardation resin and an active charcoal and alumina column. The preparation was achieved within 60 min from the end of bombardment. A neutral, sterile and pyrogen-free F-18 FDG solution was reproducibly obtained with a radiochemical yield 19.9 \pm 2.8% and a radiochemical purity of 97.6 \pm 0.6% at the end of synthesis.

This synthesis is demonstrated to be suitable for routine production of F-18 FDG.

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PRODUCTION OF N-[C11]METHYL- α -METHYL-BENZYLAMINE FOR I.V. INJECTION. K.Suzuki, O.Inoue, K.Hashimoto, K.Tamate, F.Mikado, T.Yamasaki. National Institute of Radiological Sciences, Chiba.

N-[C11]methyl- α -methyl-benzylamine (C11-MMBA) for i.v. injection was produced to study the behavior of amines in human brain.

This compound was prepared as follows: 1) production of [C11]iodomethane by the previous method, 2) reaction of [C11]iodomethane with 30 μl α -methyl-benzylamine in 0.5 ml DMF containing 10 μl of 1N-NaOH at 50°C for 1 min., 3) purification of reaction mixture by HPLC, 4) elimination of solvent with a rotary evaporator, 5) dissolution of C11-MMBA with 11 ml of saline and filtration with 0.22 μm Millex filter, 6) quality control of the product. The above procedures 1)-3) were carried out automatically with a specially designed equipment.

Irradiating the pure nitrogen (150 mm thick, 14 kg/cm²) with 14.2 MeV protons at 10 μA for 30 min., 50 - 110 mCi of C11-MMBA was obtained. The specifications of the product were as follows: specific activity; 1 - 2.6 Ci/ μmol , radiochemical purity; >99 %, amount of starting material; <1 μg , pH; 3, pyrogens and bacterias; free. The times required for the preparation of the product and quality control were 25 min. from EOB and 2 min. from EOS, respectively. The product was used clinically.