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QUALITY CONTROL SYSTEM FOR SHORT-LIVED RADIOPHARMACEUTICALS.

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Althouth 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 programable, 3) several chromatograms are obtained with γ-ray spectrum.

Using the system, quality control for $^{13}NH_3$, ^{11}C-Ro15-1788 and ^{11}C-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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AN AUTOMATED SYNTHESIS SYSTEM OF F-18 FDG WITH ACETHYLHYPO[F-18]FLUORITE IN CLINICAL USE.

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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-acethyl-D-glucal in fluorotrichloromethane at -78℃, (3) hydrolysis with 1N HCl, (4) purification of F-18 FDG by passing the hydrolysate through an ion-retadation 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±2.8% and a radiochemical purity of 97.6±0.6% at the end of synthesis.

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

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[^{18}F]FLUORIDE PRODUCTION SYSTEM USING ENRICHED ^{18}O-WATER AS A TARGET.

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A reproducible and efficient production of [^{18}F]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]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]F$^-$ yield was 70 %(170 mCi) with a 5 mm target thickness and silver backing window at a 20μA 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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PRODUCTION OF N-[C11]METHYL-α-METHYL-BENZYLAMINE FOR I.V. INJECTION.

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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 ul α-methyl-benzylamine in 0.5 ml DMF containing 10 ul 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 um 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/cm^2) with 14.2 MeV protons at 10 uA 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/umol, radiochemical purity;>99 %, amount of starting material ;<1ug, 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.