QUALITY CONTROL SYSTEM FOR SHORT-LIVED RADIOPHARMACEUTICALS.
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 the 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 the product 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 ACETETHYLHYPO(F-18)FLUORITE IN CLINICAL USE. Y. Miyake, Y. Ichia, Y. Kusabara, Z. Ayabe and A. Yoshikura,* Faculty of Medicine, Kyushu University and Radiosotope Center Kyushu University, Fukuoka.

It is well known that electrophilic addition using F-18 acetylhydofluorite(AcOF) has provided a better radiochemical yield and shorter than that using F-18 Fz. 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 consists of four processes as follows: (1) F-18 AcOF generated in gaseous phase from sodium acetate trihydrate, (2) reaction of 3,4,6-tri-0-acetyl-1-glycal in fluorinetrichloromethane at -78°C, (3) hydrolysis with 1NHCl, (4) purification of F-18 FDG by passing the hydrolysate through an ion-extradation 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 routine production of F-18 FDG.

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[14F]FLUORIDE PRODUCTION SYSTEM USING ENRICHED 18O-WATER AS A TARGET. R.Iwata, T.Ido, M.Momma, F.Brady, T.Takahashi and A.UnlIsh, Tohoku University, CYRIC and School of Medicine, Sendai.
A reproducible and efficient production of [14F] with enriched 18O-water has been studied for its use in synthesis of 18F-radiopharmaceuticals by nucleophilic substitution reactions. 1.5-2.5 mL of 20% enriched 18O-water were irradiated by 18 MeV protons with up to 20 μA currents in a Ti target vessel. Production yields of [14F]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 [14F]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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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 DMP 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 um Millex filter, 6)quality control of the product. The above procedures 1-3) were carried out automatically with a specially designed equipment.
1) 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; >7 μg, pH; 3, pyrogens and bacteria; free.
2) The times required for the preparation of the product and quality control were 25 min. from EO8 and 2 min. from EOS, respectively. The product was used clinically.