Abstract número: 48

SODIUM FLORIDE-18F: PREPARATION AND QUALITY CONTROL.

Souza AA; Herrerias R; Bruzinga W; Negrini A; Fukumori NTO; Matsuda MMN; Sciani V; Mengatti J; Barboza MF.
IPEN-CNEN/SP.

The use of 18F-fluoride for bone scintigraphy dates back to the early days in the 1950s and 1960s. Several decades before the introduction of modern PET system, 18F-NaF was recognized as an excellent radiopharmaceutical for skeletal imaging. Sodium fluoride-18F (18F-NaF) has the desirable characteristics of high and fast bone uptake accompanied by very rapid blood clearance, which results in a high bone-to-background ratio in a short time. The purpose of this work was to describe the development and validation of 18F-NaF production and quality control at the Radiopharmacy Directory. For clinical application 18F- is easily produced in a cyclotron utilizing a one step reaction 18O(p,n)18F, with enriched water H2180 (> 95%) as target: with short irradiation time (15–30 minutes). After bombardment, the target water was passed through an ion-exchange column (QMA-light, Waters) to trap the 18F-fluoride while the enriched water was eluted and collected for discarding or reusing. The 18F-fluoride was eluted off with 0.5 M sodium bicarbonate solution / 0.3mL. The final product (18F-NaF) was diluted with 15 mL of 0.9% saline solution and sterilized m Millipore filter to a sterile pyrogen-free?by passing into a 0.22 vial and final pH 5.0–8.0. The doses were fractioned according to demand. A thin layer chromatography system was carried out for radiochemical purity determination in ITLC-SG (Al) (1 x 12 cm), using acetonitrile:water (95:5) as solvent. Stability of 18F-NaF was determined immediately and 4 hours after the end of process. Radionuclides purity was determined by the radioactivity decay curve during 125 minutes. Sterility tests were performed by the microbiology procedures outlined in the pharmacopoeias in different culture media 2.5 °C. The apirogenicity was ??2 °C and at 32.5 ??incubated at 22.5 evaluated using the "in-vitro" Limulus (LAL) test. The radiochemical purity of 18F-NaF was (99.85 ± 0.08)% in 10 batches, with t1/2 = 110 minutes and the sterility and pyrogen tests negative in all delivered vials. The labeling and quality control procedures under cGMP condition have been developed and validated at Radiopharmacy Directory of IPEN-CNEN/SP and the first clinical application was successfully performed.