PRODUCTION OF ^{123}I-MIBG AT IPEN-CNEN/SP

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Sodium [^{123}I]iodide is obtained in a Cyclone 30 (IBA) at IPEN-CNEN/SP. The production process uses the following nuclear reaction: ^{124}Xe (p,2n)$\rightarrow^{123}$Cs$\rightarrow^{123}$Xe$\rightarrow^{123}$I. The ^{124}Xe gas is highly enriched (>99.8%) which results in ultra pure ^{123}I end product. The water cooled target (internal volume = 75 mL) is machined from aluminium alloy. In front of the target there are two helium cooled molybdenum windows and an alignment system consisting of a pair of four sector collimators. The irradiation is performed with protons of 30 MeV energy and an effective beam current on target of 60–70 μA. The ^{124}Xe transference from the storage bottle to the target and the recovery of the gas after irradiation and return to the bottle is made cryogenically with liquid nitrogen through stainless steel pipes. The [^{123}I] activity on the wall of the target is rinsed with sterile water and the [^{123}I] active solution (60–70 mL) is transferred to the hot cell. With a ^{124}Xe gas pressure (without proton beam) of 2 bars, about 220 MBq/μA of ^{123}I at end of bombardment was obtained.

The labelling process is based on the copper(I) assisted exchange radioiodination methods using MIBG sulphate, $(NH_4)_2SO_4$ and $CuSO_4$ at 165–170°C for 30 min. Some groups have reported that radiochemical purity after the exchange radioiodination was sufficient and that no further purification was needed. From these data, the preliminary conclusion is that 1% benzyl alcohol and a low temperature (–10°C) are effective stabilizers of ^{123}I-MIBG solutions over 24 h. Addition of 1% benzyl alcohol and storage at 4°C resulted in a fourfold reduction of the formation rate of free [*I]. Amartey [1] concluded that temperature and benzyl alcohol had a slight cumulative effect in retarding decomposition and the product remained above 90% for over 7 d at the lower specific activities [2, 3].

After the reaction time has elapsed, the vial is cooled to room temperature and a sterile saline–benzyl alcohol 1% solution is added. The volume is adusted until a desirable radioactive concentration is achieved. The active solution is sterilized through a 0.22 μm Millipore filter. After quality control aproval, the final product is delivered to nuclear medicine centres.

The radiochemical and radionuclide tests of ^{123}I are determined with Whatmann 3MM paper (1.5 cm × 12 cm) in 85% MeOH (R_f $*I^-$ = 0.75 and R_f $*IO_3^-$ = 0.40) and by γ ray spectroscopy using a HPGe detector, before the labelling procedure. The radiochemical impurity of ^{123}I–MIBG is evaluated in a fast paper chromatographic system: Whatman 3MM (1 cm × 8 cm), in n-butanol, acetic acid and water (5:2:1) as a solvent.

The values are: R_f ^{123}I–MIBG = 1.0 and free [^{123}I] iodide = 0.0 [4, 5]. The retention of ^{123}I solution in a strong anionic resin is greater than 99% and the recovery of ^{123}I–Na is more than 97% of total activity in 3 mL of 0.02N NaOH. The radionuclide purity of ^{123}I–Na and the radiochemical purity of ^{123}I–MIBG are >98% and >97%, respectively, in 90% of all routine production during a 24 h period at low temperature, without any purification step (Tables 1 and 2). The SD is less than 1.0%.

The microbiological analysis is determined in a different culture medium which is incubated both at room temperature and at 33 ± 2°C. The apirogenicity is evaluated using the 'in vitro' Limulus test. The method was developed, validated and simplified to extend it to large scale productions at the IPEN-CNEN/SP radiopharmacy centre.

During 2004, 129.5 GBq of ^{123}I–Na and 48 GBq of ^{123}I–MIBG in 37 batches, respectively, were distributed to approximately 28 hospitals and nuclear medicine centres in Brazil.

TABLE 1. RADIOCHEMICAL PURITY OF ^{123}I –Na AND ^{123}I –MIBG IN PAPER CHROMATOGRAPHIC SYSTEM

Batch (n = 37)	^{123}I–Na	^{123}I–MIBG
M	98.89	97.68
SD	0.26	0.35

TABLE 2. STABILITY OF ^{123}I –MIBG KEPT AT LOW TEMPERATURE

Batch (n = 37)	1 h	24 h
M	98.81	97.72
SD	0.30	0.58

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