

Production and supply of pharmaceutical grade Na[¹⁸F]F injection, from RC, BRIT Kolkata

¹⁸F-fluoride is a valuable imaging modality of the skeleton. ¹⁸F-fluoride PET is highly sensitive for detection of malignant and benign bone abnormalities, for monitoring response to therapy, separation between uneventful and impaired healing processes of bone fracture, osteonecrosis and graft incorporation. The production of ¹⁸F was achieved by irradiating H₂¹⁸O (1.8ml) using IBA niobium target assembly with 18 MeV, 25-30μA proton beam current (total beam on target 25μAh). The synthesis of Na[¹⁸F]F was carried out with modified IFP cartridge (IFP cartridge for FDG production has been modified) in IBA synthera module with indigenously developed software programme. The automated fluorination module using IBA Synthera module and graphics based schematic for radiopharmaceutical synthesis of Na[¹⁸F]F are represented in Fig. 1 and Fig. 2, respectively.

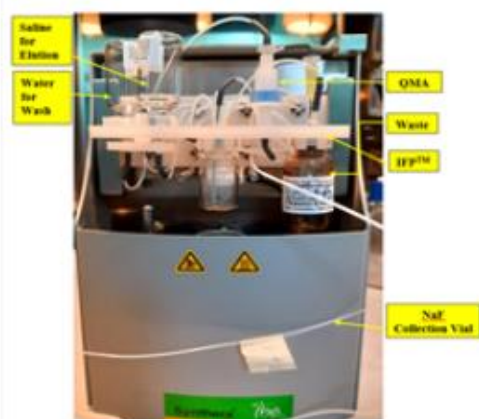


Fig. 1 : Automated Fluorination module:
For synthesis of Na[¹⁸F]F

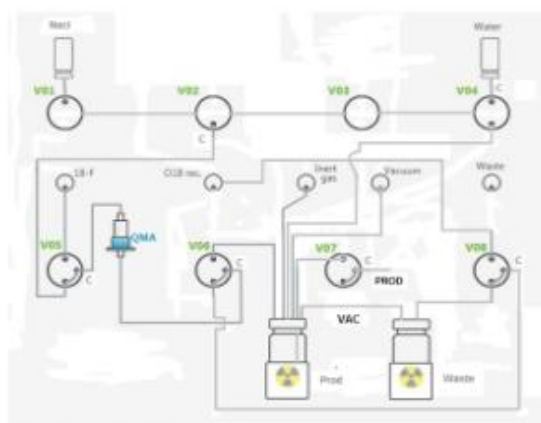
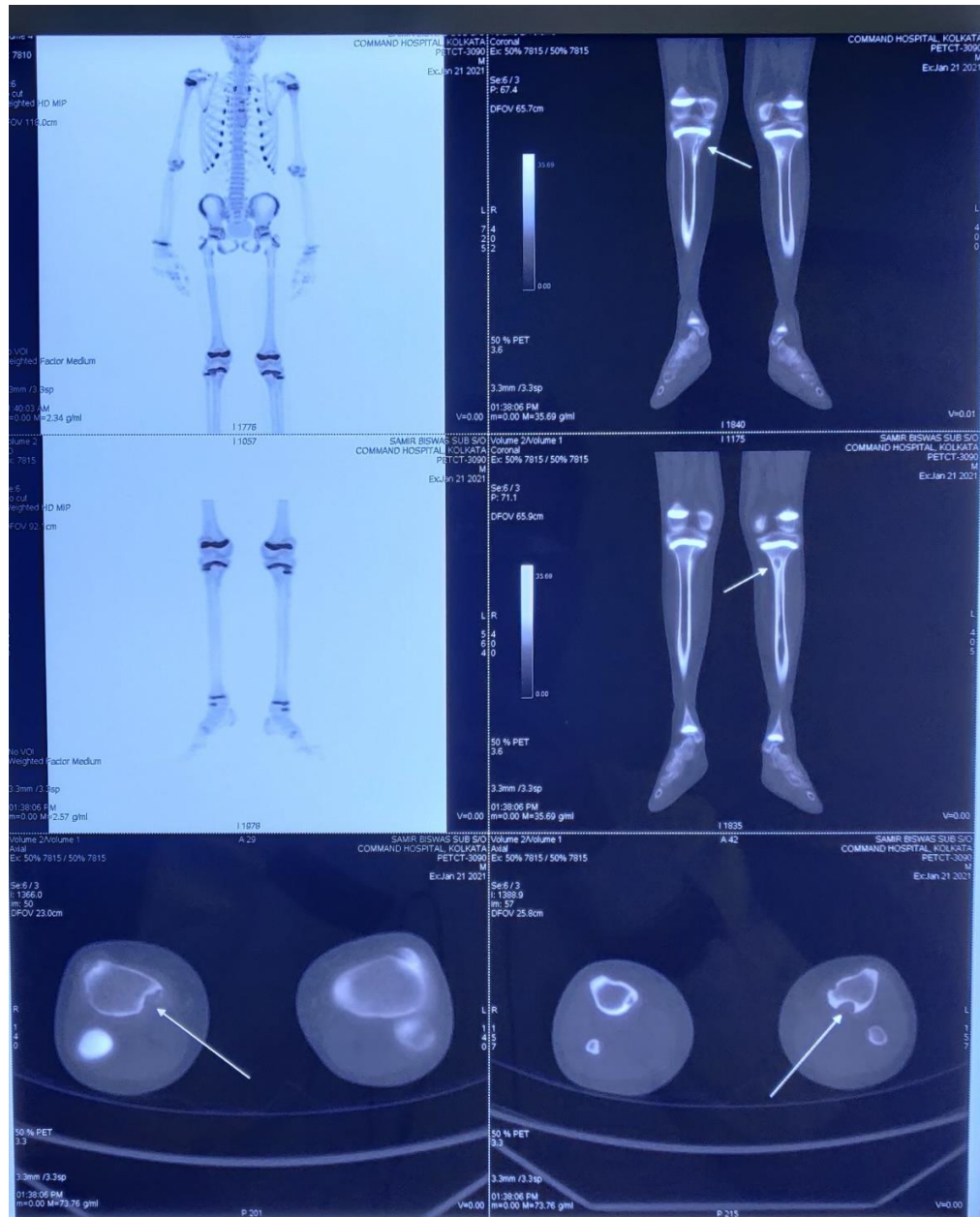


Fig. 2 : Graphics based GUI interfaced Schematic
for synthesis of Na[¹⁸F]F

The production yield of Na[¹⁸F]F is >99% and the radioactive concentration is 2-50 mCi/ml. The radiochemical purity of the Na[¹⁸F]F has been found to be 99.9%. The radionuclidic purity was greater than 99.99% (determined by HPGe) The concentration of ethanol in Na[¹⁸F]F was found < 4000. The Bacterial endotoxin in the Na[¹⁸F]F was found <5 EU/ml determined by PTS method and passed the sterility test. The production of Na[¹⁸F]F in cyclone-30 has been achieved successfully.

This new product has been launched in December, 2020.



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To
Dr Sankha Chattopadhyay
Scientific Officer-H
Regional Centre, BRIT
Medical Cyclotron Facility
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Chakgaria, Kolkata
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Subject: Feedback on 18F-NaF from BRIT, Kolkata

Respected sir,

1. I am highly obliged and grateful to you for your cooperation and availing us 18F-NaF for bone scan.
2. We conducted bone scan on 21 Jan 2021 using GE discovery 690 PET/CT scanner. Our patient was a child with diagnosis of suspected McCune Albright syndrome, where the clinician wanted to look for any bone scan evidence of fibrous dysplasia.
3. The 18F-NaF produced by BRIT, Kolkata gave excellent quality images (I am sharing the images as attachment).
4. I suggest that production of 18F-NaF should be done on a regular and larger scale by BRIT cyclotron. I also highly recommend other centres to use this radiopharmaceutical for bone scans.
5. We are looking forward to avail this radiopharmaceutical from BRIT, Kolkata on a regular basis in future.

Yours sincerely!

(Signature)
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Dated: 27 Jan 2021
Place: Kolkata-27