Annexure – I

Integrated Fluid Processor(IFP) for production of ^{18}F-FDG using IBA Synthera module.

1. **Introduction**

   For production of ^{18}F-FDG using IBA Synthera module Integrated Fluidic Processor, a combination of two plates, interconnected with tubes (IFP) is required for holding the Reagent vial and ancillary **.**

2. **Quantity : 35 No**

3. **Detail description**

3.1 Integrated Fluid Processor :

The Integrated Fluidic Processor (IFP) for synthesis of ^{18}F-FDG using IBA Synthera module is a single use sterilized IFP pack. The Integrated Fluidic Processor (IFP) consists of 8 valves, connecting port for F-18, He, etc., one reaction Vial and it has provision to house the reagents and ancillaries for FDG production. The Integrated Fluidic Processor is plastic make and consists of two plates, one horizontal and one vertical plate, (as shown in fig. 1,in Annexure –II, Integrated Fluid Processor with Synthera) hold each other and well interconnected by tube.

The vertical Plate (Ref. Plate 1 of fig.1) comprised of 8 rotary valves and 5 ports (holes) for different external connections through Synthera unit. Among these 5 ports, 4 are used for transfer of F^{18}, O^{18}, Helium/Nitrogen gas and Vacuum respectively. The fifth port is used for product /waste. The Rotary Valves are actuated by the Synthera unit. The location of these process connections and rotary valves shall be such that it matches perfectly to the respective location on Synthera.

Horizontal plate (Ref. Plate 2 in fig.1) comprised 4 reagent vial holders, 1 Reaction Vial, 2 cartridge holders, integrated interconnecting tubes and programmed RFID tag.

The 4 reagent holders in which Cryptand solution vial compatibles with vial holder 1 (internal dia 13 mm), Mannose triflate in dry acetonitrile vial compatible with vial holder 2 (internal dia 10 mm), Sodium hydroxide solution vial compatible with vial holder 3 (internal dia 10 mm) and Sterile water vial holder compatible with vial holder 4 (internal dia 13 mm) (Refer plate 2in fig 1).

The two cartridge holder (both having internal dia 4.1 mm) to be assembled with the ancillary set. Among these two Cartridge holder one (Refer plate 2 in fig 1) compatibles with combination of SCX, Alumina and C18 column and QMA column (Refer plate 2 in fig 1) All steps of the ^{18}F FDG synthesis are restricted to the Integrated fluidic processor (IFP), which is disposed at the end of the synthesis.

The Integrated fluidic Processor (IFP) unit is to be used in IBA make Synthera to produce F^{18} FDG thus The Integrated Fluidic Processor should be compatible with IBA make Synthera.

4.0 Acceptance Criteria :

1. The items should be GMP compliant (Certificate/Documents should be attached stating that the item is manufactured according to GMP requirements).
2. The IFP carrying box should have valid Lot No, RF-ID Lot No, Manufacturing Date, Expiry date etc.
3. Expiry date should be at least 11 months from the date of shipment.

5.0 Special Clause :

The item is very critical and one IFP set will be used for one single run of FDG production using IBA Synthera Module in the Medical Cyclotron. Therefore the components should be compatible with IBA SYNTHERA Module.