

INITIAL EXPERIENCE OF F-18 FDG PRODUCTION USING ABT (DOSE-ON-DEMAND CYCLOTRON) AND TRASIS (ALL-IN-ONE SYNTHESIZER) AT PKLI & RC LAHORE

M.Manan Bhatti, Shahid Younis, Amjad Rashid, Dr. Khalid Nawaz, Talha Rafiq, Yasir Hafeez
Pakistan Kidney and Liver Institute & Research Center Lahore

CONCEPT

The local production of F-18 FDG is vital for Positron Emission Tomography (PET) imaging, ensuring timely availability and reducing reliance on external supply chains. Establishing a GMP-compliant radiopharmacy facility in Pakistan requires careful validation of equipment, processes, and staff training.

- AIMS & OBJECTIVES
- To share the initial operational experience of F-18 FDG production at PKLI using the ABT (Dose-on-Demand Cyclotron) and TRASIS (All-in-One Synthesizer).
 - To evaluate workflow optimization and quality control practices.
 - To present the outcomes from our first 100 successful routine production

METHODOLOGY

F-18 was produced via the ABT (Dose-on-Demand Cyclotron) and labelled into F-18 FDG with the TRASIS (All-in-One-Synthesizer) under

GMP-compliant conditions. Each production run (n=100) was subjected to routine QC testing according to Ph.Eur specifications. Environmental monitoring and complete GMP documentation were maintained for all runs.

RESULTS & DISCUSSION

The results are present in the table.

Test	Results
Physical Appearance	Clear, Colorless & free from particulate matter
pH	5.3
Energy	510 KeV
Half Life	109.14 hrs
ITLC Labelling Efficiency	97.85 %
F18-FDG (HPLC)	98.80 %
FDM (HPLC)	0.14 %
Acetonitrile (GC)	5.66 ppm
Ethanol (GC)	2036 ppm
Kryptofix Test	< 2.2 mg/ml
Endotoxin Level	1.46 EU/ml
Osmolality	330 mOsmol
Filter Integrity Test	4.7 bar

PKLI’s experience demonstrates the successful integration of state-of-the-art technology for consistent and reliable production of F-18 FDG. The completion of 100 consecutive successful productions confirms the robustness of the system, effective staff training, and adherence to SOPs. Key challenges such as initial equipment calibration, supply chain management, and environmental control were addressed through systematic planning and continuous improvement.

CONCLUSION

Our initial experience with the ABT (Dose-on-Demand Cyclotron) and TRASIS (All-in-One Synthesizer) has shown that GMP-compliant F-18 FDG production is feasible, safe, and reliable in Pakistan.

The achievement of 100 successful productions strengthens confidence in local radiopharmaceutical supply and provides a model for further expansion of nuclear medicine services in the region.