Product Quality Review of the [^{18}F]FDG radiopharmaceutical

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AIMS

A Product Quality Review (PQR) is an essential tool for analysing and verifying the consistency of established and validated production processes as well as the quality of the produced radiopharmaceuticals.
This study aims to present the Annual PQR for [^{18}F]FDG radiopharmaceutical produced during the year 2024, at the University Institute for Positron Emission Tomography, Skopje, Republic of North Macedonia.

METHODS

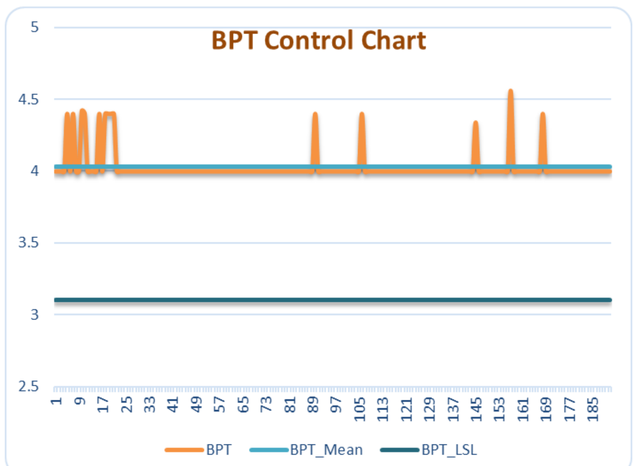
A retrospective study was performed on all [^{18}F]FDG batches produced in 2024.
The PQR covered:

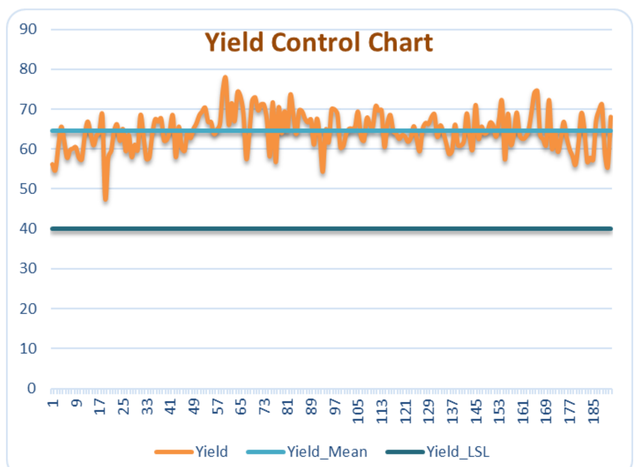
i. number of manufactured and released batches;
ii. starting materials/consumables and their compliance with specification for starting materials;
iii. in process controls including decay-corrected radiochemical yield and bubble point test (BPT) results;
iv. quality control (QC) results of finished product and trending against final product specification (appearance, radionuclidic identity, pH, radiochemical purity/identity by TLC, residual solvents, radionuclidic purity, bacterial endotoxins and sterility);
v. out-of-specification (OOS) results and investigations;
vi. deviations;
vii. status of equipment qualification/calibration and preventive/corrective maintenance;
viii. complaints, and
ix. change control, including revised and newly introduced procedures.

RESULTS

Quality Parameter		Specification	Mean ± SD	Capability	Conclusion
APPEARANCE		Clear, colourless	/	/	All batches compliant
IDENTIFICATION:	Half-life	1.75–1.92 h	1.83 ± 0.01	C_p=2.62, C_{pk}=2.39	Highly capable
	Retention time diff.	≤ 30 s	26.3 ± 1.2	C_{pu}=1.06	Within specification
	pH	5.0–8.0	7.2 ± 0.25	/	All batches compliant
CHEMICAL PURITY	Kryptofix	≤ 0.22 mg/mL	/	/	Not detected
RADIOCHEMICAL PURITY	[^{18}F]FDG	≥ 95%	100%	/	Within specification
	[^{18}F]F in the form of fluoride and other unidentified peaks ≤ 5%	≤ 5%	Not detected	/	Not detected
RESIDUAL SOLVENTS	Ethanol	≤ 5000 µg/mL	649 ± 170	C_{pu}=9.02	Highly capable
	Acetonitrile	≤ 410 µg/mL	48.7 ± 46	C_{pu}=2.59	Highly capable
RADIONUCLIDIC PURITY		≤ 0.1%	(1.87 ± 1.74) x10^{-06}		Well within limits
ENDOTOXINS		≤ 17.5 IU/mL	≤ 5		Within specification
STERILITY		Sterile			All batches sterile

Category	Result	Details
Batch production	194 batches	193 released, 1 rejected
Batch release rate	99.5%	High process consistency
OOS events	1	Root cause: operator error; CAPA implemented
Deviations	15 total	5 major, 1 critical, 9 minor
Complaints	0	No complaints reported
Equipment	Qualified	Routine maintenance and qualification performed
Change control	8 SOP changes	4 revised, 4 newly implemented





CONCLUSION

From the annual Product Quality Review of the finished product [^{18}F]FDG radiopharmaceutical, it can be concluded that the production process is stable, consistent and GMP-compliant, ensuring that the finished product consistently meets the specifications for [^{18}F]FDG solution for injection, as well as the incoming material comply with approved specifications for the quality of starting materials.