Gruppo Interdisciplinare di Chimica dei Radiofarmaci
XI Congresso Nazionale, 8-10 Maggio 2026 Pisa

OPERATIONAL PERFORMANCE AND GMP RELIABILITY OF THE TRASIS ALL-IN-ONE MODULE IN ROUTINE MULTI-PRODUCT PET RADIOPHARMACEUTICAL PRODUCTION

Salvatore Limpido[1], Marco Dicanio[2], Francesco Martelli[2], Anna Notaro[3], Letizia Guiducci[1], Michela Poli[1]

[1] Institute of Clinical Physiology, CNR, Pisa, Italy
[2] Curium Pharma, c/o CNR Pisa
[3] Curium Pharma, Gif sur Yvette Cedex, France
salvatorelimpido@cnr.it

Introduction. Automated synthesis modules are essential for GMP-compliant fluorine-18 PET radiopharmaceutical production, supporting robustness, reproducibility and operator radiation protection [1–3]. However, despite the widespread adoption of automated platforms, long-term real-world performance data in multi-product routine GMP settings remain limited [1-4].
Materials and methods. A retrospective analysis was performed in a GMP PET radiopharmacy using two Trasis All-in-One modules in parallel during 2025. Production data for [^{18}F]FDG, [^{18}F]DCFPyL and [^{18}F]FET were collected from batch records and quality systems in line with current CGMP recommendations [3-4]. Key indicators included synthesis runs, batch success rate, site and module service reliability, non–decay-corrected radiochemical yield, radiochemical purity, out-of-specification events, deviations and CAPA, reflecting established radiopharmaceutical quality assurance concepts. Failure causes were categorized as module, cyclotron, dispensing-related or other.
Results. A total of 341 runs yielded 305 released batches (overall site reliability: 89.44%). Released batches included [^{18}F]FDG, [^{18}F]DCFPyL and [^{18}F]FET, and most failures were linked to cyclotron or dispensing issues rather than module malfunction. Module service reliability was higher than overall site reliability, reaching 97.18% for [^{18}F]FDG and 98.08% for [^{18}F]DCFPyL. Mean radiochemical yields were 70.52% ([^{18}F]FDG), 41.80% ([^{18}F]DCFPyL) and 53.65% ([^{18}F]FET), with radiochemical purity consistently meeting acceptance criteria and no evidence of long-term drift. Only few deviations and OOS events were attributable to the modules and were mainly related to ancillary components or consumables rather than to the module design.
Conclusion. The Trasis All-in-One module demonstrates high robustness, reproducibility and GMP reliability in routine multi-product PET radiopharmaceutical production, in line with expectations for modern automated [^{18}F] platforms [2-4]. Overall, the system does not appear to limit manufacturing performance and supports both high-throughput routine use and the implementation of innovative fluorine-18 tracers within current PET imaging and regulatory practice [1-4].

[1] Elsinga PH, Todde S, Penuelas I, et al., Radiopharmaceuticals for PET and SPECT imaging: current status and future perspectives, Eur J Nucl Med Mol Imaging 2016, Vol. 43, 157–170.
[2] Tredwell T, Gouverneur V., Automation in fluorine-18 radiochemistry, Chem Commun 2012, Vol. 48, 7247–7260.
[3] Chi Y-T, Chu P-C, Chao H-Y, et al., Design of CGMP production of 18F- and 68Ga-radiopharmaceuticals, Biomed Res Int 2014, Vol. 2014, 680195.
[4] Crisan G, Moldovean-Cioroianu NS, Timaru D-G, et al., Radiopharmaceuticals for PET and SPECT imaging: a literature review over the last decade, Int J Mol Sci 2022, Vol. 23, 5023.