

## Development of Colorimetric Analysis Software for 2.2.2-Kryptofix Compliance Testing in [18F]FDG Production

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[18F]fluorodeoxyglucose ([18F]FDG) is a glucose analog where the hydroxyl group in the C-2 position is substituted by the cyclotron-produced [18F] radionuclide. This radiopharmaceutical is used in medical imaging, particularly in positron emission tomography (PET) scans crucial in cancer diagnoses and monitoring. 18F-FDG synthesis involves a nucleophilic substitution with 2.2.2-Kryptofix as a phase-transfer catalyst. However, Kryptofix residue quantities must be strictly regulated due to their toxicity. Current quality control processes employ spot testing where sample colors are compared to that of a standard, which is prepared at maximal Kryptofix concentration of 0.5mg/V. This project aims to build a user-friendly interface able to determine whether a [18F]FDG sample passes the Kryptofix concentration test through image analysis techniques. A Python-based application was developed using the “Tkinter” library to create a graphical user interface, integrated with image processing features. The software employs colorimetric analysis by quantifying pixel intensity and performing statistical comparisons on user-defined cross-sections of the image. Software validation is performed using images with known sample and standard concentrations. The user-friendly interface aims to improve accessibility and limit the subjectivity of human analysis for the determination of 2.2.2-Kryptofix contents in a sample and successfully determines the pass/fail status of the sample regarding regulatory safety standards of 0.5mg/V. The software generates reports documenting the analytical process, which are required for regulatory compliance and quality assurance documentation. These reports are crucial in the case of a test failure or deviation. Further improvements can be made to the software to quantify the Kryptofix concentration in [18F]FDG samples rather than provide only pass/fail data. The basic software architecture has also been adapted and modified to conduct other quality control tests in a radiopharmaceutical laboratory, with promising preliminary testing for bacterial colony counting and environmental monitoring.

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