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DEVELOPMENT AND IMPLEMENTATION OF [18F]NAF RADIOPHARMACEUTICAL PRODUCTION AT UNIVERSITY INSTITUTE OF POSITRON EMISSION TOMOGRAPHY

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[^{18}F]NaF injection is a sterile solution of fluorine-18 in the form of Sodium fluoride intended for visualization of metastatic bone disease. The automated full GMP in-house production process of [^{18}F]Sodium fluoride was developed on the dispensing module Clio.
The production module uses a single-use kit for dispensing doses. During the GMP process development, the kit was modified. On the first valve of the dispensing kit additionally were installed a one-way Y-connector and quaternary methyl ammonium anion-exchange cartridge (QMA). One end of the Y-connector was connected to the [^{18}F]F- cyclotron transfer line, while the other proximal end was connected to the saline vial for [18F]F- elution. Initial experiments were conducted utilizing various cartridge types and conditions to optimize the production process, followed by both cold and hot tests.
The developed fully automated GMP in-house method was validated, before being implemented in clinical practice. To ensure the microbiological safety of [^{18}F]NaF produced aseptically, validation of the aseptic production and cleaning validation were conducted. The stability study proved that the produced [^{18}F]NaF is physiochemically and microbiologically stable, up to 10 hours after the end of synthesis. Furthermore, the process validation was conducted to prove the reproducibility of the [^{18}F]NaF production process.
The validation results confirmed that the produced [^{18}F]Sodium fluoride fulfils the quality requirements stated in the European Pharmacopoeia monograph and can be used safely and effectively for its intended purpose.

Key words: [^{18}F]Sodium fluoride, development, production process, validation