

OPTIMIZATION OF FINAL PRODUCT DMAE CONTENT IN [¹⁸F]FLUOROCHOLINE PROCESS USING DOUBLE IBA SYNThERA® PROCESS

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As a part of enlarging the range of radiopharmaceuticals available in the Czech Republic, ÚJV Řež, a. s., the primary manufacturer of PET radiopharmaceuticals in the country, aimed at implementing a [¹⁸F]fluorocholine process using IBA Synthera V2 module platform. The production was implemented and clinical evaluation started. Recently, with the official release of fluorocholine monograph in European Pharmacopoeia (EP). **(07/2016:2793)**, a necessity to modify the process in order to comply with the maximum allowed limit for dimethylaminoethanol (DMAE) content arose. In cooperation with IBA Synthera team, a series of experiments were planned and run on the platform, aimed at optimizing the residual content of DMAE in the final product by adding ammonia solution to the synthesis process, as suggested by Slaets et al. [1]

Several synthesis runs (n=10) were performed with gradual reduction in the concentration of the ammonia solution (from 6% NH₃/ethanol to 0.1% NH₃/ethanol), and the minimum required concentration of ammonia to be added in order to meet the current EP specifications for residual DMAE.

The collaboration between our company and IBA will continue and final validation runs will be performed for an [¹⁸F]fluorocholine updated process. Afterwards, the new process is going to be used in the future production of [¹⁸F]fluorocholine in the Czech Republic.

1. Slaets D1, De Bruyne S, Dumolyn C, Moerman L, Mertens K, De Vos F. *Reduced dimethylaminoethanol in [(18)F]fluoromethylcholine: an important step towards enhanced tumour visualization*. Eur J Nucl Med Mol Imaging. 2010 Nov;37(11):2136-45.