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Lectura recomendada

Improved quality control of [¹⁸F]fluoromethylcholine

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Nuclear Medicine and Biology

Volume 38, Issue 8, November 2011, Pages 1143-1148

Abstract

Objectives

With respect to the broad application of [¹⁸F-*methyl*]fluorocholine (FCH), there is a need for a safe, but also efficient and convenient way for routine quality control of FCH. Therefore, a GC-method should be developed and validated which allows the simultaneous quantitation of all chemical impurities and residual solvents such as acetonitrile, ethanol, dibromomethane and *N,N*-dimethylaminoethanol.

Methods

Analytical GC has been performed with a GC-capillary column Optima 1701 (50 m×0.32 mm), and a pre-column deactivated capillary column phenyl-Sil (10 m×0.32) in line with a flame ionization detector (FID) was used. The validation includes the following tests: specificity, range, accuracy, linearity, precision, limit of detection (LOD) and limit of quantitation (LOQ) of all listed substances.

Results

The described GC method has been successfully used for the quantitation of the listed chemical impurities. The specificity of the GC separation has been proven by demonstrating that the appearing peaks are completely separated from each other and that a resolution $R \geq 1.5$ for the separation of the peaks could be achieved. The specified range confirmed that the analytical procedure provides an acceptable degree of linearity, accuracy and precision. For each substance, a range from 2% to 120% of the specification limit could be demonstrated. The corresponding LOD values were determined and were much lower than the specification limits.

Conclusions

An efficient and convenient GC method for the quality control of FCH has been developed and validated which meets all acceptance criteria in terms of linearity, specificity, precision, accuracy, LOD and LOQ.



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