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Quantification of drug metabolites in the absence of authentic standards

Filip Cuyckens[1], Balázs Klencsár[2], Valerie Koppen[1], Ronald de Vries[1], Cis Van Looveren[1], Bjorn Meermann[2], Lieve Balcaen[2] and **Frank Vanhaecke[2]**

[1]Pharmacokinetics, Dynamics & Metabolism, Janssen R&D, Beerse, Belgium

[2]Department of Analytical Chemistry, Ghent University, Ghent, Belgium

Quantification of metabolites in the absence of an authentic standard is a challenging task. Metabolites are usually present in relatively low concentrations residing in a large background of endogenous compounds and their MS response factor can significantly differ from the parent molecule. The use of a radiotracer overcomes these challenges and, therefore, remains the method of choice for quantification of metabolites in complex matrices, but is not always available or cannot always be applied. Typically samples from first-in-human studies are not radioactive but still extremely valuable giving a first insight in human metabolism. Therefore, estimation of metabolite abundance in these samples is important and also recommended by regulatory guidelines (ICH M3).

An overview will be given of different established and novel approaches for the quantification of metabolites in *in vitro* and *in vivo* matrices in the absence of authentic standards. The following techniques will be discussed: radioactive detection[1], Accelerator Mass Spectrometry (AMS), UV detection, Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)[2-4] and Electrospray Ionization-Mass Spectrometry (ESI-MS) using matrix mixing[5] or a $^{12}C/^{14}C$ isotope ratio approach[6].

Depending on the circumstances (sample volume, sample matrix, compound structure, question to be answered, availability of a radiolabel, etc.) the right tool or combination of tools need to be selected since none of these techniques should be seen as the standard technique that suits all measurements.

Biography

Filip Cuyckens is a Scientific Director & Fellow at Janssen R&D in Beerse, Belgium. He is responsible for Analytical Sciences in the Pharmacokinetics, Dynamics & Metabolism (PDM) department. Analytical Sciences PDM consists of Biotransformations, focusing on metabolite profiling and identification of discovery to late development compounds, and Discovery & Exploratory Bioanalysis, focusing on quantification of drug candidates, metabolites and biomarkers in biological matrices. Filip earned a pharmacist degree in 1998, a degree in industrial pharmacy in 2002 and a Ph.D. in pharmaceutical sciences in 2003.He has (co)authored more than 50 publications, is a member of the associate editorial board of Rapid Communications in Mass Spectrometry and board member of the Belgian Society for Mass Spectrometry.

FCUYCKEN@its.jnj.com

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