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Mutagenic impurities in pharmaceuticals: ICH M7, purge factors and the Mirabilis project

Mutagenic impurities are a special category of impurities that can be present in active pharmaceutical ingredients. The understanding, detection, and control of MIs have received increasing industry and regulatory attention over the past decade. Originated by Teasdale in 2010, the concept of purge factor calculation to understand the fate of MIs in synthetic processes has been validated by various independent groups, including its application to a development project at MSD that was described in a recent publication. This approach can reduce the burden of analytical testing for MIs without compromising patient safety, provided a scientifically rigorous approach is taken, backed up by sufficient theoretical and/or analytical data. Moreover, specific reference to this method is provided in the accepted regulatory guidance – ICH M7 Option 4 - which was released in 2014. This presentation provides some background to the concept of purge factor calculation and introduces a consortium-led initiative, the Lhasa Mirabilis Project. The Mirabilis consortium seeks to develop an industry-standardized approach, providing an expert and scientifically robust software for the automated calculation of purge factors for potentially mutagenic impurities in a synthetic route.

Biography

Mark McLaughlin received his PhD from Strathclyde University under the joint supervision of Prof. Kerr and Prof. Pauson. He completed two Post-doctoral appointments at the University of California, Berkeley with Prof. Rapoport and Prof. Heathcock. He received further education at the ETH, Switzerland (Prof. Diederich) and additional industrial experience at GSK (Medicinal Chemistry) and Astrazeneca (Process Chemistry). He joined MSD in 2003 as a Senior Research Chemist and is currently a Principal Scientist. In addition to Project Leader responsibilities for the development of novel chemical processes supporting new drug applications, he has served as a Subject Matter Expert within the Process Chemistry Department at MSD on the topic of Mutagenic Impurities.

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