

Multidimensional Chromatographic Techniques Supporting Pipeline Development

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As compounds progress through clinical development, the presence of challenging separation problems is inevitable. Among these hurdles are the identification of impurities or degradants from non-compatible LC methods, the separation of complex chiral mixtures, and the detection of low-level or poorly ionizing impurities. The common theme among these problems is the ability to find a solution through the implementation of multidimensional chromatography. Several case studies demonstrating the impact of 2D LC techniques will be presented, covering a diverse set of modalities in various stages of clinical development. The techniques highlighted will focus on online desalting and high resolution sampling for peak purity assessment. In addition, the development of a technique enabling the identification or quantitation of sub-LOD analytes will be discussed.