Evolution of Multi-Dimensional Chromatography from Research to Main Stream Pharmaceutical Analysis
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ABSTRACT

In the past decade, improvements in two-dimensional liquid chromatographic (2D-LC) instruments along with enhancement in software capabilities has transformed 2D-LC from the hands of experienced researchers to analytical laboratories around the world. 2D-LC offers novel solutions to problems ranging from complex samples requiring excessively large peak capacity to simple, yet difficult to resolve compounds. Recent developments in 2D-LC and 2D-LC-MS have clearly demonstrates the potential of this technique and is becoming an essential tool in modern day pharmaceutical industry.

The presentation will cover real world applications of 2D-LC-MS in assessing stability-indicating method for potential co-elution, monitoring on-column conversion, addressing dynamic range issue of one-dimensional chromatography, analysis of residual genotoxic impurities in the midst of main component differing significantly in their concentration (>10^5), simultaneous quantitative achiral-chiral analysis of chiral compounds. In addition, attributes critical for the progression of 2D-LC from research to quality control environment like linearity, accuracy, LOD & LOQ and precision will be discussed. In addition, design and application of 2D-LC-SFC in simultaneous achiral-chiral analysis will be presented.

BIOGRAPHY

C.J. Venkatramani is a senior scientist at Genentech USA and has over 20 years experience in the pharmaceutical industry. He was a key member of the Genentech technical team instrumental in the successful launch of Genentech’s first small molecule Erivedge, leading from development to commercial. Erivedge is currently approved in several countries for the treatment of advanced basal cell carcinoma (BCC). He has several publications, national and international presentations on multidimensional separation. Over the years, he has successfully used multidimensional chromatography to address challenging problems commonly encountered in pharmaceutical industry. His areas of interest include 2D-LC, 2D-LC-SFC, ultra-trace analysis of genotoxic impurities and elemental impurities.
SUMMARY

Senior Scientist with over 20 years of experience in major pharmaceutical companies providing analytical strategies and solutions to projects ranging from early stages of drug development to commercial products

EDUCATION

Ph. D. in Analytical Chemistry, Southern Illinois University, Carbondale, IL
  Advisor: Late Professor John B. Phillips, Ph.D.
  Thesis: Comprehensive Two-Dimensional Gas Chromatography
MS in Analytical Chemistry, University of Bombay, India
BS in Analytical Chemistry, University of Bombay, India

EXPERIENCE

Genentech, South San Francisco, CA August 2013 - Current
Senior Scientist, SMPS

Genentech, South San Francisco, CA 2007 – July 2013
Scientist, SMPS

Abbott Labs, North Chicago, IL
Research Investigator, Global Pharmaceutical R&D

Searle/Pharmacia/Pfizer, Skokie, IL
Scientist, Chemical Development & Global Supply

Mallinckrodt Inc, St Louis, MO
Analytical Research Scientist, Imaging R&D

The Procter and Gamble, Cincinnati, OH
Summer Intern
DOSSIERS

NDA and MAA SUBMISSIONS

NDA & MAA authoring of Genentech’s first small molecule Erivedge - Control and Stability Sections, Dossier Designer and Reviewer, Dossier PAI, Risk Mitigation Strategy and Regulatory Defense

PATENT APPLICATION

C. J. Venkatramani and Mohammad Al-Sayah, “Systems and Methods for Two-Dimensional Chromatography (2D LC x SFC)”, GNE Ref Number: P32332-US-PR; MoFo Ref: 14639-30281.00

WEBINAR


PUBLICATIONS


ORAL PRESENTATIONS


4) C. J. Venkatramani, Mohammad Al-Sayah, Ila Patel, Larry Wigman, Jacob Kay, Meenakshi Goel and Shu Rong Huang “High-resolution analysis of linker drugs used in ADC’s by 2D-LC-MS; Transition of 2D-LC-MS from research to main stream pharmaceutical analysis”, HPLC2017, Prague, Czech Republic, 2017.

6) C. J. Venkatramani, Rolf Schulte Oestrich and Andrew Marriott, Round Table Discussions on Genotoxic Impurities, Knect365, Prague, Czech Republic, 2017


13) CJ. Venkatramani and Mohammad Al-Sayah, “Extending Capabilities of Multi-Dimensional Chromatography in Pharmaceutical Analysis – 2D LCxSFC”, Roche AHM, Ireland, 2014.


18) C. J. Venkatramani, James Girotti, Larry Wigman and Nik Chetwyn, Applications of two-dimensional liquid chromatography in pharmaceutical analysis, HPLC2013, Amsterdam, Netherlands, 2013.


POSTER PRESENTATIONS


5) C. J. Venkatramani and Yury Zelechonok, “Two-dimensional liquid chromatography with the same mixed mode stationary phase in both dimensions”, HPLC2003, Nice, France, 2003.

6) C. J. Venkatramani, Anurag Patel and Yuri Zelechonok, “Comprehensive two-dimensional
