North Jersey Chromatography Group
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Chromatography: New Techniques and Applications

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Abstacts/Bios.

Development and Validation of a RP-HPLC method for the Determination of Gentamicin Sulfate and its Related Substances in a Pharmaceutical Cream using a short Pentafluorophenyl column and a Charged Aerosol Detector

Arul Joseph, PhD
Senior Scientist, Merck & Co., Inc.

Abstact: Gentamicin sulfate is a potent broad spectrum aminoglycoside antibiotic. A reversed-phase high performance liquid chromatographic (RP-HPLC) method was developed and validated to determine the composition of gentamicin sulfate and to estimate its related substances (without any pre- or post-column derivatization) in a pharmaceutical cream. As gentamicin has a weak UV chromophore, it is not possible to detect low levels of known and unknown related substances of gentamicin using a UV detector. In this method, a Charged Aerosol Detector (CAD) was used to obtain high sensitivity that was necessary for the intended purpose of the method. This method can separate all the analogues of gentamicin including all known and unknown related substances.

Bio: Arul Joseph is a senior scientist at Merck & Co., Inc. He received his PhD in Organic Chemistry from the University of Maryland in 2001 and was the California Breast Cancer Research Program Postdoctoral Fellow at the Scripps Research Institute from 2001-2004. He has published articles in analytical chemistry, organic chemistry, proteomics, and intellectual property.

Sub 2-Micron HPLC Columns - Looking Beyond ODS Phases

Matthew Przybyciel, PhD
Vice President, ES Industries

Abstract: Reversed-phase HPLC is widely used for separation of many pharmaceutical compounds. A majority of these separations are based on ODS type columns. However, retention and separation of various compounds have proven to be a challenge. Many of these types of compounds are unretained, poorly retained or unseparated on most conventional reversed-phase stationary phases, such as ODS. Fortunately, to deal with these types of compounds alternative (non-ODS) stationary phases can be utilized using polar, fluorinated and other non-hydrocarbon based stationary phases. These columns can to be used in the traditional reverse phase mode as well as "hydrophilic interaction chromatography" or HILIC. HILIC chromatography uses mobile phases containing between 5 - 20 % water for the retention of polar compounds. These new HPLC columns packed with 1.8 um particles have been engineered to specifically for high pressures. We will show examples on how applications can benefit from the performance of 1.8 um particles with non-ODS phases. We will demonstrate how these HPLC columns can provide for the high resolution separations over a wide variety flow rate conditions and mobile compositions.

Imaged Cappilary Isoelectric Focusing: A Rapid Approach to Study Charge Heterogeneity in Therapeutic Protein

Jin Qian, PhD

Senior Research Scientist, Bioventure

Bio: Jin Qian is currently a senior research chemist in Bioventure of Merck & co. INC. Her research interests are develop analytical methods to support bioprocess development. Prior to Merck, Jin worked as a senior scientist for Global Quality services-analytical sciences in Schering-Plough corporation after postdoctoral fellowships with MIT and UMDNJ. She earned a Ph.D. from Swedish University of Agricultural Sciences, Sweden in 2001.

The SFC Advantage

Thomas DePhillipo

Regional Technical Specialist, Waters Corp.

Abstract: Recent years have witnessed an exponential increase in the adoption rate of Supercritical Fluid Chromatography (SFC) in both chemical and pharmaceutical industries. The intrinsic low viscosity and high diffusivity of supercritical CO2 has rendered SFC higher separation speeds and efficiency than traditional LC. SFC also readily lends itself as a complementary alternative to reversed phase LC because of its normal-phase-like separation mechanism. Furthermore, the use of supercritical CO2 as the mobile phase significantly reduced the usage of organic solvents, making SFC a green technology.

With significant improvement in pumping technology and availability of sensitive detectors over the years, the application areas of SFC have evolved from its original petrochemical, pharmaceutical analyses to a much wider range of fields including, but not limited to, the analyses and/or purifications of food, flavor and fragrance, natural product, and environmental protection.

In this presentation, the fundamentals of supercritical fluids and Supercritical Fluid Chromatography, including the physical properties of supercritical CO2 and their implication in separation will be illustrated. Several different detection methods will be reviewed, and a cost analyses on some real cases will be presented to highlight the "green" aspect of SFC.

Bio: Tom graduated from St. Joseph's University in 1995 with a degree in Chemistry. Immediately after graduation he worked for the injectable division of Wyeth Ayerst , where he was involved in developing analytical methods for active pharmaceuticals using various analytical. He then went on to work for Dionex Corporation for 6 years as an application chemist in the sales department. Tom joined TharSFC in 2006 as a Regional Technical Specialist. His main responsibilities include performing feasibility studies for customer's samples, developing new applications for SFC and doing technical presentations and demonstrations for various product lines.

Development of Chromatography Steps for Monoclonal Antibody Purification

Yan Yao, PhD

Senior Scientist, Bioventure

Bio: Yan Yao is a senior scientist in Bioventure of Merck &Co. INC. working on late stage downstream process development in Protein Purification & Characterization. Prior to Merck, she worked for Bristol-Myers-Squibb doing bioanalytical assay development in Biotechnology Development. She earned a Ph.D. in Chemical Engineering from University of Delaware.

A Mathematical Based UPLC-MS Approach to Dry Powder Inhaler Content Uniformity

Justin Pennington, PhD

Associate Principal Scientist, Merck & Co., Inc.

Abstract: The development of dry powder inhaler (DPI) products requires the assessment of blend uniformity at various stages of the manufacturing process, including formulation blends and the final drug product agglomerates. Uniformity testing for DPI products has the unique challenge in that a single unit dose is typically on the order of one milligram, standing in contrast to oral solid dosage forms which are typically in the hundreds of milligrams. The small sample size increases the analytical tests' dependence on measurement of an accurate sample weight, thereby significantly increasing the time associated with sample preparation and analysis. While traditional HPLC content uniformity methods are suitable for release testing of DPI products, they do not offer the efficiency required to analyze the hundreds of samples per day that can be generated while conducting formulation development activities.

In order to quickly and accurately determine the blend uniformity of DPI products, an ultra performance liquid chromatography - mass spectrometry (UPLC-MS) based content uniformity method was developed to provide a rapid, simple, and accurate measurement. Through the use of mathematical modeling and proper selection of bracketing standards, a volumetric approximation of sample weight can be utilized that eliminates the need for accurate sample weight and reduces sample preparation time. Further time savings was achieved by utilizing UPLC to shorten the chromatographic run times and mass spectrometry to achieve the necessary selectivity. The resulting UPLC-MS method for content uniformity resulted in an approximate 10-fold efficiency gain over traditional approaches and successfully served to support the high demand of formulation development activities.

Bio: Justin Pennington is currently an Associate Principle Scientist at Merck working in the Respiratory Development group. He has focused on integration of mass spectrometry into all facets of product development. He joined Schering-Plough, now Merck, in 2007 and was promoted to his current position in 2009. He received his PhD from the Department of Pharmaceutical Chemistry at the University of Kansas in 2006. His dissertation project focused on the development of fluorescent stable isotope tagging strategies for proteins containing DOPA. Justin is a 2002 graduate of Briar Cliff University in Sioux City Iowa with a BS in Math and Chemistry.