Nanomedicine & Biotherapeutic Discovery

Extended Abstract

Ion Chromatography Solution for Applied Pharmaceutical Markets

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Abstract

An accurate understanding of the contents of any pharmaceutical entity helps to ensure both drug efficacy and patients safety. Over several decades, there has been significant improvements in the analytical methods and techniques ensuring critical quality attribute analysis of the pharmaceutical products. The solutions offered by Dionex Ion Chromatography systems are widely adopted and are everyday gaining more traction because of the several technological advancements and benefits in these Dionex IC systems. These advancements include superior accuracy, high-throughput, improved reliability, and environmental safety concerns which significantly contribute towards the critical analysis of the drug entity of interest. IC primarily relies on suppressed as well as non-suppressed conductivity detections for ionic species in pharmaceutical samples. Dionex IC systems can accurately analyze multiple anions/cations in a single injections, thereby, accelerating the analysis throughput. The productivity can be further improved by converting the single channel system to a dual-channel system where two different samples can be concurrently analyzed. Most recent advancement, Consumables Device Monitor, can automatically identify and tracks the installation time, use, and performance metrics of all the installed IC consumables. This feature can reduce any associated downtime due to consumable installation errors and can even schedule preventive maintenances. Such smart capabilities can significantly improve the productivity as well as lessen the burden on the analysts time in a fast-paced pharmaceutical laboratory. All modern IC systems can make eluents automatically, allowing the consistent and reliable production of high purity IC eluent concentrations. The only routine reagent then needed is high-purity water. Consequently, the instrument pump seals and pistons only come into contact with deionized water instead of acids and bases which can precipitate. This extends the lifetime of pump seals and pistons, and significantly reduces the overall pump maintenance requirements. Dionex IC systems are constantly evolving with the changing times and needs. Recent IC systems are equipped with a tablet supporting 11 different languages with an intuitive interface.

This tablet control enables direct local control of the system and its status. All these enhanced capabilities and advancements has only led to the successful adoption of IC for analyzing ionic species in pharmaceutical applications.

As dictated by the nature of the analyte, IC has been applied to all aspects of the manufacturing and disposition of pharmaceutical products, including the characterization of drug substances and active ingredients, excipients and other “inert” product components, degradation products and/or impurities and process streams components. The following sample types are analyzed: starting raw materials, intermediates (including media and culture broths), pharmaceutical raw materials, diluents, formulated products, production equipment cleaning solutions, and waste streams. The method is especially valuable in the pharmaceutical industry for ionic analytes (in products containing non-ionic components) that have little or no native UV absorbance.

However, the ability to couple the ion exchange separation with numerous detection strategies expands IC applications to instances were analyte-specific detection strategies can provide the required degree of sensitivity and/or specificity. Utilization of such strategies allows for IC applications to be implemented on appropriately configured HPLC systems. Additionally, ion exclusion separations expand the range of application of IC to nonionic analytes of significant pharmaceutical interest including alcohols and carbohydrates. The wide dynamic range of the methodology makes it applicable for the quantitation of trace contaminants as well as major product components. Ion chromatography (IC) has developed and matured into an important analytical methodology in a number of diverse applications and industries, including pharmaceuticals. This manuscript provides a review of IC applications for the determinations of active and inactive ingredients, excipients, degradation products, and impurities relevant to pharmaceutical analyses and thus serves as a resource for investigators looking for insights into the use of the IC methodology in this field of application.

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