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Impurity determination in pharmaceuticals by Ion Chromatography–Pulsed Amperometric Detector (IC-PAD)

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Ion Chromatography (IC) is recently gaining popularity for determining impurities in pharmaceuticals. The ionic separation mechanism gives IC a different separation selectivity than reversed-phase HPLC. Pulsed Amperometric Detection (PAD) coupled with anion-exchange chromatography is a powerful technique to determine the compounds that undergo oxidation or reduction at a noble metal surface. The current generated is proportional to the analyte concentration, which can be detected and quantitated. For many drugs or their impurities that lack UV chromophores, PAD provides an alternate simple and sensitive detection method. IC-PAD has been used extensively for direct detection of monosaccharides, oligosaccharides, amino acids, proteins, and glycoproteins.Two case studies of impurity determination by IC-PAD will be discussed in this presentation. The first study is an anion-exchange IC method coupled with PAD proposed by USP for determination of galactosamine in total hexosamine in Heparin drug substance. Galactosamine can be formed from any oversulfated chondroitin sulfate, dermatan sulfate and other galactosamine-containing impurities in Heparin drug substance upon acid hydrolysis. Galactosamine was separated from glucosamine by IC and determined by PAD. The verified galactosamine range in Heparin is 0.4 to 2.1%, with LOQ at 0.29%. The second study is for determination of Beta Cyclodextrin (BetaDex) in Betadex Sulfobutyl Ether Sodium (BSES) raw material by IC-PAD also proposed by USP. BetaDex is the starting material to synthesize the sulfobutyl ether derivatives and the BetaDex limit is 0.1%. Because of poor UV signal, detection of Cyclodextrin (CD) is always a challenge. Evaporative light scattering detection, mass spectrometry, conductivity, and indirect UV detection have been used for detection of CD. However, poor sensitivity or selectivity, long analysis time, and difficulties for operation make these methods unfavorable. In this case study, BetaDex was determined by IC-PAD from 0.05% to 0.15% in BSES raw material. Both of these methods have been successfully evaluated and verified in the R&D laboratory with respect to specificity, accuracy, precision, linearity, range, LOQ and LOD.

Biography

Xiaohui Yang completed her Masters degree in Analytical Chemistry from Southern Illinois University, Carbondale in 1999 and since then she has worked as an Analytical Chemist in pharmaceutical industry for the past 13 years. Her work experience includes drug pharmacokinetic support by LC/MS/MS at Pfizer and Eli Lilly Co., and analytical method development for drug products at Baxter Healthcare Corporation.

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