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QA/QC of monoclonal antibodies: Bio-separations solutions for biopharma

M. Sundaram Palaniswamy
Agilent Technologies Inc, India

Monoclonal antibody therapy is used for many diseases such as rheumatoid arthritis, multiple sclerosis and different types of cancers. The antibodies (or mAb) specifically bind to target cells or proteins, which then stimulate the patient's immune system to attack those cells. It is possible to create a mAb specific to almost any extracellular/ cell surface target. There is a large amount of research undergone for the development of therapeutic monoclonal antibodies. Like all other protein therapeutics, mAb can undergo structural modifications derived from oxidation, deamidation, aggregation or amino acid substitution etc during production, storage and transportation. Therapeutic monoclonal antibodies (mABs) are characterized by a variety of assays to warrant drug safety and efficacy. In this study we demonstrate several tools for QA/QC of monoclonal antibody (IgG1) using Bio-chromatography. RP HPLC for peptide mapping and disulfide linkage analysis, Size exclusion chromatography (SEC) for purity and aggregation analysis and Ion exchange chromatography (IEX) to detect charge state variant due to truncation, deamidation oxidation and glycosylation. Simple and reproducible methods suitable for the QA/QC analysis of therapeutic biologics will be discussed in this presentation.

Biography

M. Sundaram Palaniswamy obtained his PhD in Bio-Chemistry from Karnatak University, Dharwad in 2005. He served as Scientist at GangaGen Inc, Bangalore from April 2005 to Dec 2011. During his tenure with GangaGen he was leading the Protein purification group and developed novel methods for the purification and characterization of bacteriophage and phage derived recombinant proteins. He accomplished successful completion of Pre-clinical toxicity studies of an anti-Staphylococcal protein P128. Currently he is working as Application Scientist at Agilent Technologies Inc. Bangalore. His areas of interest in Biopharma include- LC, LC/MS and electrophoresis platforms.

hisundarji@gmail.com