Andras Guttman, J Bioanal Biomed 2017, 9:3(Suppl)
http://dx.doi.org/10.4172/1948-593X-C1-026

Multilevel characterization of biosimilars by CE-LIF and CE-MS

Andras Guttman
University of Pannonia, USA

Statement of the Problem: Recent increase in biosimilar development in the market triggered rapid development of comprehensive and reproducible multilevel characterization methods at all levels of the bioprocessing pipeline for the biopharmaceutical industry and regulatory agencies. One of the largest groups of biosimilars is monoclonal antibodies (mABs), possessing various post-translational modifications (PTMs) and potential degradation hotspots, which should be analyzed during clone selection, manufacturing and lot release as possibly affecting efficacy and immunogenicity.

Methodology & Theoretical Orientation: The exceptional separation power of capillary electrophoresis (CE) in conjunction with laser induced fluorescence or high resolution mass spectrometry fulfills the multilevel characterization requirements.

Findings: Level-1: Determination of accurate molecular mass and some degree of heterogeneity at the intact glycoprotein level; Level-2: Measurement of exact molecular mass of the heavy and light chains as well as the degree of heterogeneity after reduction of the disulfide bonds with or without alkylation; Level 3: Characterization of degradative hotspots such as asparagine-deamidation, methionine-oxidation, glutamic-acid-cyclization, C-terminal lysine heterogeneity and other posttranslational modifications at the peptide/glycopeptide level after proteolytic digestion of the reduced and alkylated antibody; and Level 4: Detailed glycosylation characterization.

Conclusion & Significance: A comprehensive multilevel characterization example will be given for a representative therapeutic monoclonal antibody illustrating the benefits of the integration of capillary electrophoresis (CE) with laser induced fluorescence detection (CE-LIF) and with electrospray ionization (ESI) in a unified bioanalytical process (CESI) coupled with high resolution mass spectrometry.

Biography

Andras Guttman, MTA-PE Lendulet Professor of Translational Glycomics, directs the Horváth Csaba Laboratory of Bioseparation Sciences in Hungary and leads the application efforts in Sciex in California. His work is focused on capillary electrophoresis and CESI-MS based glycomics and glyco-proteomics analysis of biopharmaceutical, biomedical and cell biology interests. He has more than 290 scientific publications, author of 35 book chapters, edited 4 textbooks and holds 23 patents. He is on the board of several international organizations, and member of the Hungarian Academy of Sciences.

guttman@mik.uni-pannon.hu

Notes: