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The use of high-speed liquid chromatography/Tandem mass spectrometry in the GLP assays for biosimilars

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Abstract

Biosimilars development demands rapid and reliable bioanalytical methods across preclinical and all phases of clinical trials to assess the similarity in the pharmacokinetic/ pharmacodynamic outcomes. Fast liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS) has become the most widely employed bioanalytical technique in quantitative determination of small molecules. In this presentation, we discuss our strategies in extending the use of high-speed LC-MS/MS approaches to biosimilars assays under good laboratory practice (GLP)-compliant setting. The impact of sample preparation methods such as protein precipitation, solid-phase extraction and immuno-precipitation prior to chromatographic separation on assay sensitivity, selectivity, accuracy will be presented. The results obtained by the proposed method were compared with those obtained by ligand-binding assays.

Biography

Dr. Hsieh received his Ph.D. from Chemistry Department of Michigan State University. During his tenure at Drug Metabolism and Pharmacokinetics (DMPK) Department of legacy Schering-Plough Research Institute/Merck Research Laboratories, Dr. Hsieh lead a strong bioanalytical group to apply challenging UPLC-MS/MS approaches for metabolite identification and sub-nanogram/ml quantitative assays of a variety of molecules and also served as a project manager to conduct in vitro and in vivo exploratory DMPK experiments for a variety of drug discovery programs such as TRA, HCV, CHK1 and to present the results in collaboration with medicinal chemistry and biology departments to support drug discovery projects.