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LCMS application for investigating stability of extemporaneously compounded preparations and studying pharmacokinetics in clinical trials

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Pharmaceutical compounding of formulation as per United States Pharmacopeia (USP) has been a major scientific challenge for hospital pharmacies across the United States. The main advantage of compounding is to have economical and customized delivery of drugs as per the patient needs in a hospital setting. Most sterile and non-sterile formulations compounded in any clinical setting are assigned with the beyond-use date (BUD) as per the standards given by USP. Limited information exists towards the investigation on the extended BUDs or degradation of the compounded formulations. Many studies have shown that the compounded preparation's active pharmaceutical ingredients (API) can have extended stabilities if stored under specific conditions. This can significantly extend the BUDs (beyond the standard recommendations) of the compounded preparations in the hospital. With the development of high resolution and sensitive liquid chromatography and mass spectrometry, it is possible to investigate extended BUDs of various formulations that hospital pharmacies develop under different temperatures, humidity, and other stress conditions. HPLC or LCMS studies have helped us to study and provide recommendations for extended stability of compounded preparations at Thomas Jefferson University Hospital Pharmacy. Our laboratory has developed highly sensitive analytical (HPLC/ LCMS) assays to study the stability of 5-FU, vancomycin, buprenorphine, lonidamine, and other preperations in their respective formulations. The assays had sensitivities in nanogram/mL concentrations with %CV and %recoveries as <5% and 100±10%, respectively. We have used these LCMS assays for determining the BUD for the compounded preparations, based on the degradation profile over time under specific storage conditions. Being an LCMS-based bioanalytical lab, we also support trials of active drug molecules in clinical and preclinical setups with our highly sensitive quantitation assays. In the present talk, we would like to share the LCMS method development stories and highlight the significance of therapeutic drug monitoring by connecting analytical laboratories to compounding pharmacies and hospitals for developing personalized therapeutic solutions.

Biography

Dr. Kaushal and Dr. Rochani's laboratory has extensive expertise in evaluation of small and macromolecules using HPLC and LCMS technologies. They have created a GLP complaint laboratory for studying stabilities of compounded formulations at hospital and PK/PD studies for known drugs and new chemical entities. They have been providing their scientific expertise inform of consultation, experimental output and academic research for various (profit and nonprofit) institutions across the United States. Their laboratory has been overseeing the formulation development and LCMS based characterization of the formulations under in vitro and in vivo conditions. They have developed LCMS assays for > 30 drug molecules and have more than a decade long experience in studying LCMS methods for small molecules in complex biological matrix. They also serve as guest editor and editorial board members of various journals like polymers, drug discovery and therapeutics and others.

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