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Designing clinical interference studies to address colorimetric assays

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The development of a drug product, SANGUINATE™ (pegylated carboxyhemoglobin bovine) with a hemoglobin molecule (Hb) as a component, creates challenges in accurately measuring clinical chemistry analytes in human and animal samples. Most clinical analytes are assayed using spectroscopic methods employing calorimetric analysis. Therefore to ensure that the results from both preclinical and clinical safety studies are accurate, it is necessary to design and execute interference studies to determine what analytes are affected by the presence of Hb from SANGUINATE and what correction factors can be used to permit accurate measurements during preclinical and clinical studies. To this end, a series of studies was designed using three animal species as well as blood samples from normal human volunteers. The study design included the use of four different methods: Clinical chemistry, hematology, coagulation and blood gas analysis using different instrumentation. The various instruments employed spectroscopic analysis, tonometry, radiometry and nephelometry. Immunologic analysis included an ELISA- based system. Using the data generated from these studies, correction factors were determined for most analytes. The results from the multispecies study demonstrated species equivalence. In general, there were very few differences among the species. Any differences were adjusted for by using species-specific correction factors. The first indication for SANGUINATE is Sickle Cell Disease which has both an ischemic and hemolytic component. Challenges still remain to measure interference in patient's samples with active hemolysis. In addition, the variety of instrumentation used in hospitals will require approaches to ensure that data generated is accurate and correlated.

Biography

Hemant Misra received his PhD from Lucknow University in Medicinal and Pharmaceutical Chemistry and has published over 55 articles and a patent. He is VP Clinical Development for Prolong Pharmaceuticals. He has over 30 years of biopharmaceutical development, global clinical study management and corporate development experience. He has managed drug development, CGMP manufacturing, CTM, quality systems and multiple global clinical trials.

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