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TITLE

Drugs, Devices and Nutraceuticals Down Under

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AnQual Laboratories, an internationally accredited GLP laboratory, in Auckland, New Zealand is celebrating 5 years of formulation, analytical science and regulatory services to drug discovery research groups, biotech, food technology and clinical teams worldwide. Drugs: Development and validation of rapid, sensitive bioanalytical methods for selective separation and simultaneous detection of drugs, such as Ketamine, and its metabolite Norketamine, in plasma, allow a better understanding of their posology and long lasting anaesthetic effect in paediatric patients. Calibration curves were linear with a coefficient of 0.99 over the range of 1ng/ml to 62.5ng/ml, and percentage RSD within acceptable pharmaceutical limits. Devices: Ambulatory and multi-chamber plastic devices for parenteral infusion therapy are now widely available to outpatients at home. Compatibilities of drugs, parenteral nutrition admixtures containing omega-3 lipids, glutamine, and other pharmaconutrients, have been investigated and recommendations made for optimum storage conditions. Light protection is essential and exclusion of air minimises potential drug-nutrient interactions or substrate oxidation. Stability profiles for various concentrations of the broad spectrum antibiotic, Amoxicillin, in Baxter Infusors, were developed from a novel validated HPLC analytical method with linear calibration, correlation coefficient of 1 and equation of y=1640x, where y represents area and x represents concentration in ug/ml. Nutraceuticals: Novel oral, topical and parenteral delivery systems of drug- nutrient combinations that minimise chemical interactions but maximise therapeutic efficacy are under development. Pharmacokinetic investigations on high dose selenium, as sodium selenite, suggest an initial bolus followed by continuous infusion is most effective in maximising antioxidant status of critically ill patients.

Biography

Gil Hardy has expertise in pharmaceutical, nutraceutical and cosmaceutical product development, pharmacovigilance, cGMP, GDP, GLP training and audits. Our highly trained scientists perform analytical validation, formulation stability and degradation studies for in vitro and in vivo investigations, to agreed timelines in well equipped internationally accredited laboratories. AnQual has extensive experience with a wide range of analytical issues and regulatory affairs, producing dossiers to meet the highest international regulatory standards. By working in partnership with industrial, health care and academic institutions, preclinical and clinical trials can be completed in a cost effective but timely fashion and speedy approval of regulatory authorities achieved.