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Emerging analytical & bioanalytical techniques and platforms for drug discovery and development -Technical and regulatory perspectives

Michael Zhou
Lachman Consulting Services, USA

Pharmaceutical and biopharmaceutical industries have led global initiatives to develop consensus around acceptable benchmark practices applicable to standardizing laboratory and good management systems for analytical and bioanalytical studies and data management in support of discovery, preclinical and clinical trials. Recent issues with analytical and bioanalytical support (novel technologies, LBAs, chromatographic based assays and so on) demonstrate the additional need for a robust quality standard for analysis and bioanalysis of biotherapeutics. Industry-wide acceptance and application of a new quality standard would assure the consistency and quality of data, applications, and products approved for public use by regulatory agencies. In addition, common issues encountered in analytical and bioanalytical assays such as selection of the reference standard curve and appropriate QC materials, fit-for-purpose assay acceptance criteria, and the pros and cons of utilizing commercial assay kits will also be discussed. The presentation will rely heavily on real life case study examples to illustrate the concepts of fit-for-purpose assay development and validation, and successful implementation of new techniques and platforms in drug development. Topic would include talks on special considerations when developing and validating assays for quantitation of analyte(s) of interest. Additional discussion points would be handling data analysis and reduction / integration to simulate PK/PD modeling for statistic evaluation. Regulatory perspectives on emerging techniques and platforms will be also discussed accordingly.

mzhou@ion-e.com

Optimization of extraction methods for phenolic and antioxidants activity in *Berberis asiatica* fruits using response surface methodology

Tarun Belwal, Amit Bahukhandi, Sandeep Rawat, Indra D Bhatt and **Ranbeer S Rawal**
G. B. Pant Institute of Himalayan Environment and Development, India

Wild fruits are known to play significant role in preventing free radicals mediated diseases. This property is largely due to the phenolics and other metabolites present in the fruits, which are reported to have strong antioxidant activity. Considering to this study was designed to optimize the extraction of phenolics and antioxidants in *Berberis asiatica* fruits using response surface methodology (RSM). Solvent selection was done based on the preliminary experiments and a three-level-five-factor, Central Composite Design (CCD) consisted of 46 experiments was conducted to analyze the effect of extraction temperature (X1: 30 – 80°C), extraction time (X2: 30 – 90 min), sample to solvent ratio (X3: 1:10 – 1:50), pH of the solvent (X4: 3 – 5) and solvent concentration (X5: 20 – 80 %) for extraction of total phenolic content (TPC), total anthocyanin content (TAC), total tannins content (TTC), and antioxidant activity [2,2-azinobis-3-ethylbenzthiazoline-6-sul- phonic acid (ABTS)]. Results revealed that extraction temperature (X1), sample to solvent ratio (X3) and solvent concentration (X5) significantly influenced response variables and independent variables. The regression coefficient (R2) was found satisfactory for all the models. The lack of fit was found non-significant ($p>0.05$) for TPC, TAC, and TTC indicating that the models could adequately fit the experimental data. Response surface analysis showed that under optimal extraction conditions the phenolic antioxidant extraction maximized. These values are in accordance with the predicted values, indicating the success of RSM in optimizing the extraction conditions. This method can be used further for scaling up nutraceutical and pharmaceutical applications and also can be implemented in other fruits of the region for harnessing their potential in commercial sector.

tarungbpihed@gmail.com