Preclinical and Clinical Analytical Services

Analytical Instrumentation

- Chromatography and separations (HPLC, UPLC, GC, IC, CE) with various detectors
- GC-MS (standard, MS/MS)
- LC-MS (MS/MS, high-resolution, ion mobility)
- Phase imaging and identification by optical microscopy (stereomicroscopy and PLM), electron microscopy (ESEM, TEM), AFM, and XRD
- Elemental analysis (ICP-OES, ICPMS, SF-ICP-MS, EDXRF, EDX)
- Physicochemical characterization (particle counting, DSC and MDSC, TGA)
- Spectroscopy (NMR, FTIR, Raman, CD, fluorescence, energy dispersive, polarimetry, refractometry)
- Particle sizing (SEC, laser light diffraction, DLS, MALS, optical and electron microscopy)
- Moisture analysis (Karl Fischer, GC-MA)
- Dissolution and disintegration testing
- Sample preparation (class 100 clean hoods, contamination controlled facilities)
- Monitored cold storage and environmental stability and photostability chambers

RTI International provides analytical support and consultation to pharmaceutical companies in preclinical through Phase III. Our expert scientists offer a full range of analytical services, from lead discovery chemistry to cGMP release of finished products. RTI's familiarity and compliance with regulatory requirements of the U.S. Food and Drug Administration and other agencies enable the clients to have complete confidence in the quality and acceptability of all analytical data.

Capabilities

- Method development and validation for active ingredients, marker compounds, impurities, and stability-indicating assays
- Test article and dose concentration analysis—purity, homogeneity, and stability
- Bioanalytical method development and validation using chromatographic assays
- High-throughput clinical sample analysis
- Inductively Coupled Plasma-based metals impurity testing (USP <232> and <233>, and biosample analysis)
- Material characterization including particle size, shape, morphology, and surface charge
- Regulatory consulting

Compliance

- Registered with the FDA as an analytical testing facility
- Registered with the DEA for scheduled drug substances
- cGMP/GLP-compliant or R&D-type feasibility studies

For more information, contact us at
analyticalsciences@rti.org

Dose Concentration Analysis

RTI developed and validated an analytical method in support of IP dose administration of the tobacco specific nitrosamine, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) in support of a commercial GLP Pre-Clinical study. This included a stability assessment in the selected vehicle to cover the dosing period which enabled them to conduct the studies with accurate concentrations and stable formulation.

Bioanalytical Method Development and Validation

RTI developed and validated a method for simultaneous analysis of reverse transcriptase inhibitors emtricitabine, tenofovir (administered orally as the pro-drug tenofovir disoproxil fumarate), and efavirenz in mouse tissues, in support of a GLP toxicology study. This included method assessment and stability determinations in maternal plasma, fetus homogenate, and pup plasma. This simple, fast UPLC-MS/MS method is being used to study toxicity following in utero exposure to this combination therapy.

Metals Method Validation

RTI conducted a method validation for mineralomic analysis to assess the potential changes in body chemistry in subjects that were taking a test formulation. The mineralomic data helped identify the potential for side effects from mineral imbalances. The entire validation was completed in a three week period to meet the client's deadline.

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