Austin Clinic – ADME Study Capabilities

Absorption, distribution, metabolism and excretion (ADME) studies are critical in understanding how a drug is processed by the human body to assess safety and toxicity. PPD's clinical research unit (CRU) in Austin, Texas holds a radioactive research license in the state and has supported over 30 early development clinical trials with more than 200 subjects involving C-14 labeled compounds. The Austin CRU provides on-site scintillation counting and has the capability to measure decays per minute (DPM) in different types of biological samples.

Austin CRU Highlights

Pharmacy Services

- USP 795/797/800 regulations compliant
- Full-time registered pharmacists (On call 24/7)
- Full-time certified technicians
- Aseptic [c14] RL/parenteral compounding room
- Early client engagement to meet any pharmacy needs
- On-site controlled access BA/BE drug retention room
- Extensive experience with complex nonsterile, sterile, radiolabeled and high-risk compounding (HRC)
- QC procedures for subject specific label and dose preparation
- Controlled investigational drug storage
- Rees® environmental monitoring system

Laboratory Services

- Wide clinical menu of tests / seven-day operations
- Bar-coded samples
- Same-day reporting
- Electronic data transfer
- Results posted to PPD data portal for sponsor viewing
- On-site liquid scintillation counting (total radioactivity measured)
- PK/PD processing lab (plasma, urine and feces)
- Flow cytometry
- Extensive library and custom assay development
- Assays run locally or processed and shipped to PPD bioanalytical lab

Aseptic [c14] RL/parenteral compounding room

Extensive experience with complex nonsterile, sterile, radiolabeled and high-risk compounding (HRC)

On-site liquid scintillation counting

Case Study: Mass Balance

Background

- Study conducted at the Austin Texas CRU
- Study drug class: opioid receptor antagonist
- Key inclusion/exclusion criteria:
  - Males up to 55 years of age
  - BMI up to 32 allowed
  - Can't have participated in another radiolabeled study in the last year
  - Can't have any problems affecting venous access or bowel/bladder function
  - No medical history with any issues affecting absorption or metabolism

PPD Strategy

- The study called for 10 subjects to be enrolled into a three-period study with two of the periods requiring C14 radiolabeled doses
- The screening and enrollment plan called for a single cohort with subject domiciled from day one to day 21
- Contingency planning accounted for the possibility of subjects needing to stay past day 21 until less than 1% of the C14 dose is recovered per day for two consecutive days
- Special menu prepared by the PPD dietitian to restrict poorly digestible foods and to increase fiber intake

Study Results

- 32 subjects screened
- 10 + four backups checked in and 10 subjects enrolled per protocol
- Blood, urine and fecal samples processed per protocol with emesis captured up to four hours post-dose for C14 analysis
- Four subjects exited on day 21 as planned, one subject exited on day 22, four exited on day 25 and one subject exited on day 28

For more information please contact us at +1 877 643 8773
or at ppdinfo@ppd.com. www.ppd.com