Pharmacokinetics (PK)/Pharmacodynamics (PD) and Mechanistics solutions in Ellegaard Göttingen Minipigs

Aragen offers comprehensive drug discovery and development solutions to assess the PK and PD of novel drugs and differentiated dosage forms using Göttingen Minipigs. Backed by a multi-disciplinary team of pre-formulation, toxicology and DMPK scientists, Aragen has a proven track record of assisting the rapid advancement of client’s programs from discovery to development stage. Aragen’s partner for in-life part of these studies, Palamur Biosciences, based out of Hyderabad, has India’s largest animal facility (GLP-certified and AAALAC-accredited) for conducting pre-clinical and regulatory studies in large animals such as Beagle dogs and Minipigs.
**Deliverables:**
- Ointment tolerability-observation of local tolerance, skin histology
- Lateral permeation
- Plasma PK profile, concentration of compound and its metabolites in tissues/urine
- Biomarker profiling
- Organ toxicity

**Topical Ointment Studies**
- Area marking
- Ointment application
- After application
- Removal of ointment & cleaning of area with alcohol swab and washing with water
- 3 hours later
- Occlusion

**Topical Patch Studies**
- Area Cleaning
- Glue liner removed
- Patch applied
- Area after patch removal
- Patch removed
- 7 days later

**Estimation of residual/resident drug content in different skin layers**

**Transdermal Patch Applied for 2 Days**

**Transdermal Patch Applied for 7 Days**
Estimation of residual/resident drug content in different skin layers

Histopathological changes in Skin post topical patch/ointment Application experiment

- Parakeratosis
- Hyperkeratosis (Tickening of Stratum Corneum)
- Ulceration (Epidermis lost)
- Inflammatory Cells Infiltration (Mixed Cells)
- Acanthosis (Stratum Spinosum layer Tickening)
- Edema

Untreated Skin: H&E 10X
Treated Skin: H&E 10X
No Histopathological Changes
Treated Skin: H&E 10X
Presence of basophilic granules in stratum Corneum (SC) indicating drug retention in SC
Aragen's Advantage

- Industry leading quality and turn around time for PK/PD and Mechanistic solutions
- Study initiation within 48 hrs of sample receipt
- Submission of report within 5 working days after study completion
- Report in MS Word/MS Excel format as per client requirement
- Qualified BA team developing sensitive rugged methods for small and large molecules in minimum time
- Access to high end instrumentation for BA of small and large molecules
- Expertise to handle different matrices like blood, plasma, urine and feces
- In-life observation, exposure levels, PK parameter analysis - Win, Nonlin rigorous QC check of data
- 19 high-end dedicated LC-MS/MS instruments for BA of small and large molecules
- Customized/Flexible protocols based on customer’s study need

Scope of work

- In life - Test compound administration and sample collection - Palamur
- Sample receipt and fit for purpose BA method development - Aragen
- Sample (plasma/serum/blood/urine/feces) analysis - Aragen
- Overall project and logistics management - Aragen

DMPK, In Vitro, In Vivo and Bioanalytical Facilities

Nacharam, Hyderabad
Non-GLP
Rodents PK

Jigani, Bengaluru
Non-GLP
Rodents+ Bioanalytical

Intox, Pune
GLP
Rodents PK

Mallapur, Hyderabad
Non-GLP
Rodents PK + Bioanalytical

Palamur, Hyderabad
GLP
In-Life studies in large animals

Let’s begin the conversation

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