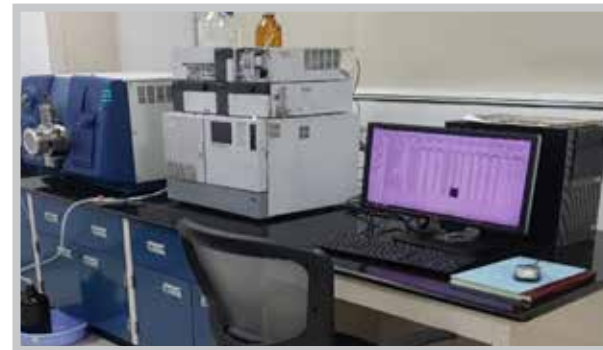


Pharmacokinetics (PK)/ Pharmacodynamics (PD) and Mechanistics solutions in Ellegaard Göttingen Minipigs



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.



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

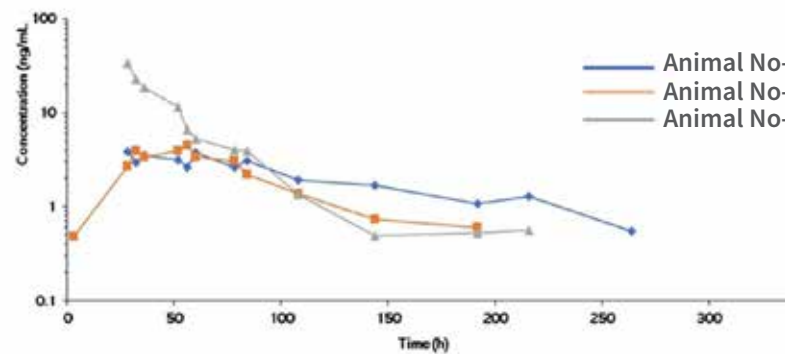
7 days later

Deliverables:

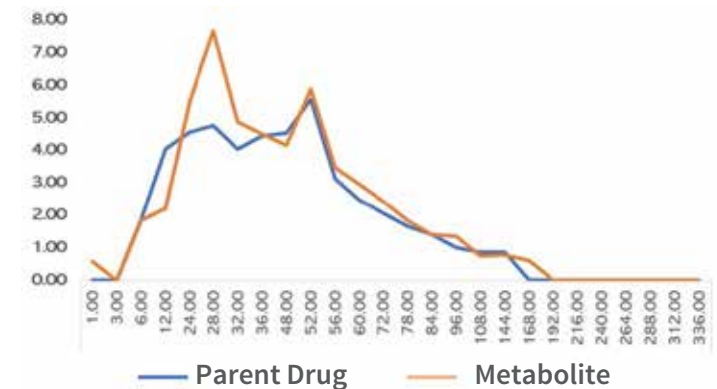
- Ointment tolerability- observation of local tolerance, skin histology
- Lateral permeation
- Plasma PK profile, concentration of compound and its metabolites in tissues/urine
- Biomarker profiling
- Organ toxicity

Estimation of residual/resident drug content in different skin layers

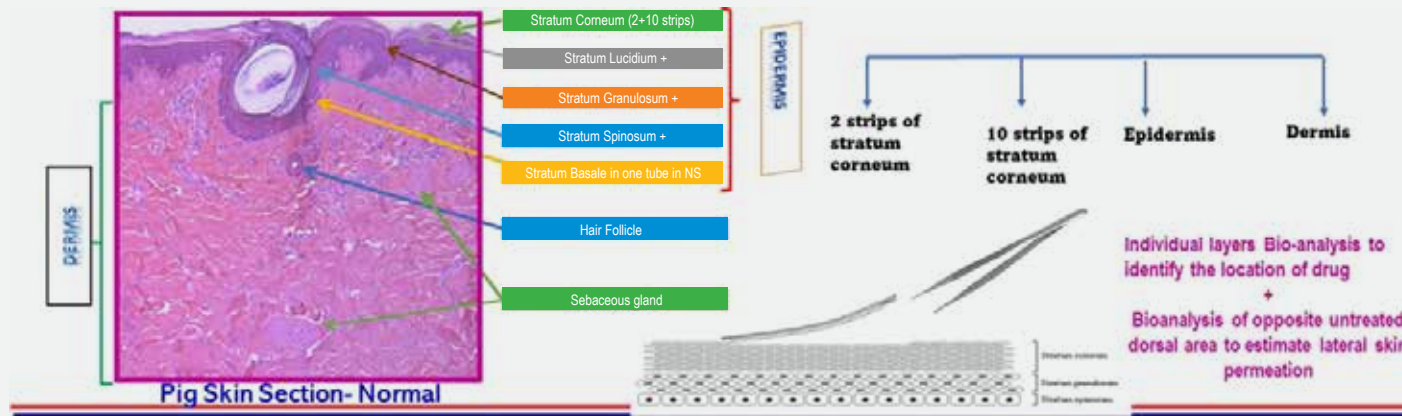
Transdermal Patch Applied for 2 Days



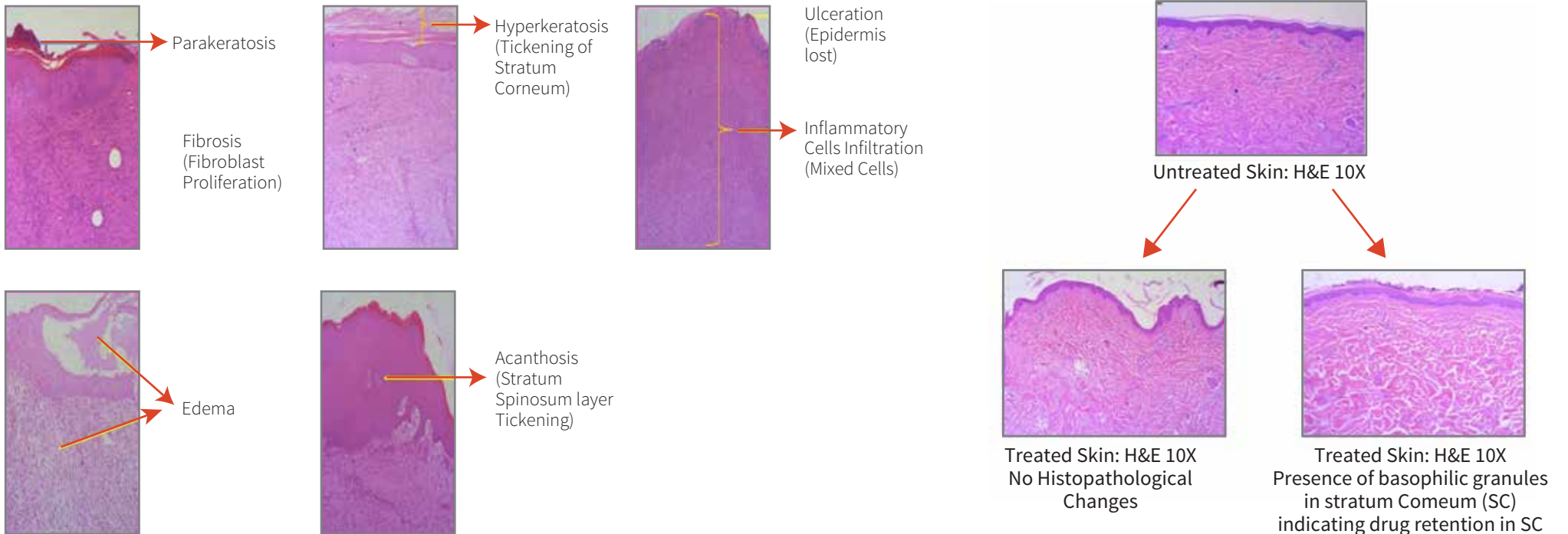
Transdermal Patch Applied for 7 Days



Estimation of residual/resident drug content in different skin layers



Histopathological changes in Skin post topical patch/ointment Application experiment



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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