



Regulatory Dermal Toxicology Testing

Sinclair personnel are experts in conducting the dermal/transdermal safety studies (GLP and non-GLP) needed for registration of a dermal or transdermal test article/device, either 505 (b)(1) or 505 (b)(2) pathways.

505 (b)(2) Regulatory Dermal Filings

- Local skin irritation in rabbits (Draize scoring, Primary Irritation Index)
- Local skin sensitization in guinea pigs (Magnusson and Kligman grading)
- Photosafety (phototoxicity and photoallergy in numerous models, including miniature swine and guinea pigs)
- Dermal toxicology (acute through 9-month minipig)

505 (b)(1) New Chemical Entity Regulatory Dermal Filings

- Local skin irritation in rabbits (Draize scoring, Primary Irritation Index)
- Local skin sensitization in guinea pigs (Magnusson and Kligman grading, etc...)
- Photosafety (phototoxicity and photoallergy in numerous models, including miniature swine and guinea pigs)
- Dermal toxicology (mouse, rat, minipig)
 - Acute, short-term (7- to 28-day), subchronic (90-day), or chronic durations.
 - Single or repeated dose (SID, BID, TID, or continual)
 - Occluded or non-occluded administration
- Ocular toxicology in rabbits (Draize scoring)
- Systemic toxicology in rodent (dose-range finding through subchronic)

For All Regulatory Dermal Studies

- A dedicated team of highly-trained technicians for dermal scoring to ensure consistency across multiple studies
- Cross-contamination prevention – custom equipment for dermal studies
- Specialized dermal evaluations as needed (colorimetry, photography)
- Dermal evaluation (Draize scoring) and local tolerance
- Passive and active (iontophoretic) dermal/transdermal patch administration
- Dose preparation
- Custom large animal enclosures for dermal studies – stainless steel full barrier
- Large capacity for chronic housing of large animals in a GLP compliant environment
- Toxicokinetics for dermal/transdermal routes of administration
- Standard toxicology endpoints – clinical observations, clinical pathology, ECG, ophthalmology, and histopathology in partnership with HSRL
- Board-certified support personnel – veterinary ophthalmologists, veterinary cardiologists, and veterinary pathologists.

Sinclair takes great pride in providing a high level of animal care and welfare and counts a high ratio of highly trained experts in its ranks. Our vivarium resides on an ergonomically and environmentally friendly designed campus. We are AAALAC-accredited, GLP & SEND-compliant, USDA, EPA & FDA inspected. We welcome your call to discuss how we can partner with you to further your development plans and nonclinical studies.