ALTASCIENCES

CASE STUDY

Antifungal Small Molecule Aerosol Application

STUDY OVERVIEW

Altasciences was contracted to conduct a safety study in minipigs involving a unique dermal dosing route of administration—an aerosol spray. For dermal studies, the regulatory expectation is to have the test article applied to 10% of the minipigs' body surface area. This is typically accomplished by applying the test article directly to the animal as a cream or ointment. With the test article being delivered by aerosol, our experts had to determine the precise amount of spray time needed to achieve the required dose. It was also necessary to ensure that the application of the test article did not result in material running off the animal.

STUDY DETAILS

- **Drug Development Phase:** pre-IND
- **Class of Drug:** small molecule
- **Therapeutic Area:** antifungal
- **Animal Model:** minipig
- **# of Animals:** 18 per sex
- **Dose Route:** dermal by aerosol
- **Dose Regimen:** once daily for eight days
- **Study Design:**
  - clinical observations
  - food consumption
  - body weights
  - Draize scoring
  - clinical pathology
  - toxicokinetics
  - anatomic pathology

STUDY PURPOSE

To evaluate local and systemic toxicity and toxicokinetic characteristics of an antifungal test article and potential reversibility of any findings.

METHODS

Miniature swine were dosed on the skin using an aerosol canister provided by the client. All animals were dosed once daily for eight consecutive days.

Standard safety observations and measurements were performed over the course of the study, including detailed clinical observations, body weights, food consumption, clinical pathology, and anatomic pathology.

Blood samples were collected periodically following dosing on Days 1 and 8 to determine systemic exposure.

Animals were euthanized on Day 9. Complete necropsies were conducted, and standard organ weights recorded. A full set of tissues was collected from all animals, processed to slide, stained with hematoxylin and eosin (H&E), and evaluated by Altasciences' board-certified veterinary pathologist.

Group	Test Material	Dose Level (mg/kg)	Concentration (mg/g)	Dose Weight of Formulation (g/kg)	Terminal		Recovery	
					M	F	M	F
1	Untreated Control	NA	NA	NA	4	4	2	2
2	Vehicle	0	0	0	4	4	2	2
3	Test Article	40	20	2	4	4	2	2

RESULTS

The sponsor provided an estimated time to deliver the desired dose level using their aerosol canisters. A test run was conducted to assess the accuracy of the sponsor-provided estimate so that we could properly plan for accurate dosing during the study.

We weighed each canister before dosing, sprayed for five seconds, then weighed the canister again. If this did not deliver the desired quantity of test material, the technician would spray for another few seconds, repeating the process until the desired weight differential was obtained. In addition, the ideal distance between the canister and the animal needed to be determined to ensure even application and avoid any runoff of the test material.

Once our experts had determined the appropriate spray duration and distance, that is what was used to dose the animals on study. To achieve consistency, the same technician who performed the trial runs conducted all the dosing events during the study.

All dosing events were documented using a form that included the animal number, the canister's start weight, start time of the spray, end time of the spray, the canister's end weight, and the animal-specific spray canister IDs.

HOW ALTASCIENCES' EXPERTISE DROVE RESULTS

Dermal studies typically involve a cream or ointment that can be weighed and applied to a specific area on the animal with a high degree of consistency. Since this study involved the test article being administered with an aerosol spray, the standard approach would not work. To achieve dosing that would be consistent and accurate, we worked out the duration of the aerosol application and from what distance.

ABOUT ALTASCIENCES

Altasciences is a drug development organization dedicated to safely accelerating early-phase development for biotech, biopharmaceutical, and pharmaceutical companies. By combining the scale and expertise of a leading CRO/CDMO with the flexibility and personalized approach of a mid-size partner, Altasciences delivers unified solutions across **nonclinical**, **clinical**, **bioanalytical,** **formulation**, and **manufacturing** services. Through intentional integration and true collaboration, the company removes barriers from lead candidate selection to clinical proof-of-concept—helping sponsors save time, reduce complexity, and make confident, data-driven decisions that enable earlier returns on investment. Guided by over 30 years of experience, Altasciences helps clients reach critical milestones faster.

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