

PRECLINICAL FORMULATIONS



Altasciences has a dedicated laboratory and office space for the preparation of formulations for use in preclinical studies. The design of the facility takes into account modern-day production demands, from test article receipt through preparation, dosing, and disposal of formulations.

MATERIAL RECEIPT

Materials are unpacked and verified to ensure that they have been transported and received in the appropriate environmental conditions, and that no damage occurred during transit. Materials are logged into our electronic management system and transferred to our storage facilities; with confirmation of receipt by email sent to the sponsor.

TEST AND CONTROL ARTICLE STORAGE

Altasciences receives hundreds of test and control articles every year. Control and test articles are stored separately, under the appropriate, sponsor-defined storage conditions: room temperature, refrigerated, frozen, and deep-frozen. All storage areas have continuous temperature monitoring and are equipped with alarm systems to ensure the integrity of the materials.

STUDY SET-UP

Our central laboratory area is dedicated to setting up the formulations requirements to support preclinical studies. In this area, we prepare the study and glassware, labels, and other equipment.

VEHICLE PREPARATION

Vehicles and controls are prepared in a dedicated vehicle/control laboratory. To prevent control article contamination, test articles are handled in a separate laboratory.

FORMULATION PREPARATION

Over 75 different formulations are prepared every week in our dedicated laboratory, fully equipped with all the necessary equipment, such as a fume hood, laminar flow hood, and Class II cabinet. A dedicated preparation room is used for vehicle/control preparation to avoid contamination.

At the end of each preparation, all equipment is cleaned, maintained, and inspected, after being used to ensure readiness for the next preparation.



FORMULATION DISPENSING

Formulations are handled and transferred daily according to a strict chain of custody to the dosing technicians, at the allotted time, having undergone any necessary manipulations (e.g., stirring and thawing). Our experts verify the materials and sign the study records to maintain the chain of custody during transfers.

GLASS WASHING

All materials used in the preparation and storage of formulations are washed by dedicated staff within the formulations area. The glass washing area is equipped with dedicated laboratory-grade dishwashers, a drying oven, and an autoclave, to ensure that all apparatus and glassware are ready for use.

DISPENSE™

Our formulations group works with Instem's Dispense™, for test article accountability. This computerized system allocates unique barcodes to test article containers, and monitors them from receipt to storage. All weights are automatically captured in the system, ensuring correct formulation preparation and real-time tracking to enhance our robust formulation processes.