

Animal Welfare and Testing Policy

Animal Testing Programmes at Lupin

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Purpose: Lupin is committed to conducting research and development in a responsible and ethical manner. This policy outlines our principles, practices and programs regarding the use of animals in research, ensuring compliance with applicable laws and promoting animal welfare.

Our research facility oversees animal testing only when legally required and in strict compliance with applicable regulatory guidelines, organizational policies, and procedures.

Scope: This policy applies across all levels of the organization within Lupin Limited, including its subsidiaries, joint ventures, suppliers, contract research organizations and partners across the value chain.

Policy: We commit to the following:

- Animal testing is considered only after a thorough evaluation confirms that no suitable non-animal methods are available.
- Ensure all animal testing complies with applicable national and international laws as applicable.
- Ensure strong Animal Welfare Standards so that animals used in research are housed in humane conditions, with unrestricted access to food, water, enrichment, and veterinary care.
- Adherence to the 3Rs Principle
 - o **Replacement:** Prioritize non-animal alternatives.
 - o **Reduction:** Minimize the number of animals used.
 - o **Refinement:** Enhance procedures to reduce pain and distress.
- Follow recognized best practice standards in animal care and be committed to pursuing relevant certifications that uphold the highest standards of animal welfare.
- Ensure alignment with global best practices in animal welfare and seek certification and accreditation from recognized bodies where applicable, such as National Good Laboratory Practice Compliance Monitoring Authority (NGCMA-OECD) and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. The Standard Operating Procedure (Refer SOP No. LRP/RAF/SOP/4018) of the Institutional Animal Ethics Committee (IAEC) governs the ethical review, approval, and monitoring of all animal research activities at Lupin.
- Ensure all studies are reviewed and approved by Institutional Animal Ethics Committee (IAEC) (Refer SOP No. LRP/RAF/SOP/4018).
- Where required, work with certified third-party laboratories that meet ethical and regulatory standards on animal testing and welfare.
- Require all third-party organization we engage to conduct animal-based research on our behalf to adhere to this Policy, associated standard operation procedures and to comply with all applicable laws and regulations.
- Ensure only trained and qualified personnel are permitted to conduct procedures.

- Maintain detailed records of all animal studies conducted.
- Conduct regular audits of all animal testing practices to ensure adherence to ethical standards, regulatory requirements, and internal policies.
- Collaborate on the development of alternative testing methods such as in vitro, in silico, and organ-on-chip technologies.
- Use animals in research and testing only when scientifically necessary and after exhausting all alternative methods.

Animal Testing Programs:

At Lupin, our animal care programs are led by qualified, skilled technical and R&D teams and experts, ensuring adherence to the highest global welfare standards. We actively invest in enrichment initiatives and alternative testing methods, supported by dedicated specialists. Our facilities consistently exceed regulatory benchmarks and maintain voluntary accreditation, reflecting our commitment to ethical research practices.

1. Commitment to the 3Rs Principle:

We are guided by the internationally recognized 3Rs principle—Reduction, Refinement, and Replacement to ensure responsible and ethical animal research:

a) Replacement: We actively seek and adopt alternatives to animal testing wherever feasible. Animal testing is considered only after a thorough evaluation confirms that no suitable non-animal methods are available.

b) Reduction: We strive to minimize the use of animals in research by ensuring that only the minimum number of appropriate species is used to achieve scientifically valid results.

c) Refinement: We continuously improve procedures to enhance animal welfare, designing methods that minimize pain, distress, and discomfort.

2. Compliance for animal testing:

To meet the regulatory compliance, following measures are implemented that provides a clear procedure for conducting research on animals ethically and maintain the quality of laboratory animals those are bred and/or maintained at research animal facility.

- a. Laboratory Animal Supply and Procurement (Refer SOP No. LRP/RAF/SOP/4009)
- b. Laboratory Animal Transportation (Refer SOP No. LRP/RAF/SOP/4011)
- c. Rodent Husbandry (Refer SOP No. LRP/RAF/SOP/4013)
- d. Rabbit husbandry and quarantine (Refer SOP No. LRP/RAF/SOP/4050)
- e. Observations of Clinical Signs and Morbidity/Mortality Check in Laboratory Animals (Refer SOP No. LRP/DSA/SOP/1000)
- f. Detailed Clinical Observations of Laboratory Animals (Refer SOP No. LRP/RAF/SOP/4029)
- g. Pest Control Program (Refer SOP No. LRP/RAF/SOP/4023)

- h. Collection and Disposal of Biomedical Waste (Refer SOP No. LRP/RAF/SOP/4025)
- i. Sterilization of the Housing and Allied Supplies (Refer SOP No. LRP/RAF/SOP/4032)
- i. Biosecurity Measures: Personnel and Material Movement in Research Animal Facility (Refer SOP No. LRP/RAF/SOP/4000)
- j. Personal Hygiene and Personnel Protective Equipment's (Refer SOP No. LRP/RAF/SOP/4031)
- k. Moping and Sanitation (Refer SOP No. LRP/RAF/SOP/4008)
- l. Fumigation of Animal Quarters (Refer SOP No. LRP/RAF/SOP/4004)
- m. Health Monitoring of Laboratory Animals (Refer SOP No. LRP/RAF/SOP/4051)
- n. Recognition of Pain and Humane Endpoints in Laboratory Animals (Refer SOP No. LRP/RAF/SOP/4036)
- o. Ectoparasite and Endoparasite Screening (Refer SOP No. LRP/RAF/SOP/4007)
- p. Chemical and Microbial Contaminant Monitoring of Animal Feed, Bedding Material and Drinking Water (SOP No. LRP/DSA/SOP/1091)

3. Quarantine Procedures:

Animals procured from registered national and overseas vendors of repute are subjected to defined quarantine procedure as prescribed by government authorities. Quarantine of animals should be done in such a way that, it should not come in direct contact with other housed animals in the facility till their successful completion of quarantine period.

Rodents are quarantined in Individually Ventilated Caging (IVC) system while the nonrodents are quarantined in individual cages. During quarantine period separate animal caretakers should handle related activities of this area.

In case of higher (additional) occupancy a separate area should be demarcated, and animals should be quarantined as per SOP No. LRP/RAF/SOP/4005 for rodents, SOP No. LRP/RAF/SOP/4050 for rabbits.

4. Animal Welfare Concerns Reporting Policy:

Any animal welfare concerns are reported by the person whosoever first observes the incidence. Lupin has an Animal Welfare Concern Reporting Policy (Refer Policy No. LRP/RAF/POLICY-3) and has appointed an Institutional Animal Welfare Officer (IAWO) to effectively handle and address the issues related to animal welfare. IAWO is independent of animal experimentation. Contact details are posted at concerned facility locations to notify any animal welfare concern observed. A drop box is provided at Research Animal Facility entrance lobby for notifying any animal welfare concern observed.

Policy also provides procedures for individuals and employees to report any concerns related to animal welfare.

All concerns are reviewed in a timely manner, and appropriate corrective actions are taken when necessary to ensure the continued ethical treatment of animals in our research programs.

5. Governance and Oversight:

Lupin Research Park serves as the governing body for implementation, overseeing and all improvements to this policy and related processes, ensuring alignment with evolving scientific standards and ethical expectations.

6. Regular Audits of Animal Testing Practices

IAEC conducts an annual facility inspection of laboratory and animal housing facilities. Also, IAEC conducts a semi-annual review of animal care and use program. Apart from IAEC, Lupin's Quality Assurance Unit (QAU) conducts routine audits and monitors all animal testing practices to ensure adherence to ethical standards, internal policies and regulatory compliance for good laboratory practices.

Changes to the Policy:

Lupin will periodically review and update this policy in consultation with relevant internal and external stakeholders to ensure that the policy statements are aligned with applicable regulations, scientific, ethical and best international pharmaceutical industry practices.



Approved by
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REFERENCES

1. Compendium of Committee for Purpose of Control and Supervision of Experiments on Animals (CPCSEA), 2018.
2. Guide for the Care and Use of Laboratory Animals, 8th edition, National Research Council, National Academies Press (US); 2011.
3. Observation of Clinical Signs and Morbidity/Mortality Check in Laboratory Animals (LRP/DSA/SOP/1000)
4. Handling of Laboratory Animals (LRP/DSA/SOP/1004)
5. Measurement of Body Weight and Food Consumption (LRP/DSA/SOP/1005)
6. Oral, Dermal, Parenteral and Rectal Dose Administration in Laboratory Animals (LRP/DSA/SOP/1006)
7. Identification of Laboratory Animals (LRP/DSA/SOP/1008)
8. Collection of Blood from Laboratory Animals (LRP/DSA/SOP/1012)
9. Necropsy and Organ Collection of Small Laboratory Animals (LRP/DSA/SOP/1014)
10. Euthanasia of Laboratory Animals (LRP/DSA/SOP/1075)
11. Gender Determination of Laboratory Animals (LRP/DSA/SOP/1094)
12. Conducting a Study (LRP/DSA/SOP/1124)
13. Repeated Dose Toxicity Studies in Rodents (LRP/DSA/SOP/1173)
14. Single Dose Toxicity Study in Rodents (LRP/DSA/SOP/1174)
15. Respiratory Safety Pharmacology Study in Rodents (LRP/DSA/SOP/1192)
16. Rodent Husbandry (LRP/RAF/SOP/4013)
17. Collection and Disposal of Biomedical Waste (LRP/RAF/SOP/4025)
18. Detailed Clinical Observations of Laboratory Animals (LRP/RAF/SOP/4029)
19. Recognition of Pain and Humane Endpoints in Laboratory Animals (LRP/RAF/SOP/4036)
20. Operation of Radio Frequency Identification (RFID) Readers (LRP/RAF/SOP/4047)
21. Rabbit Husbandry and Quarantine (LRP/RAF/SOP/4050)
22. Health Monitoring of Laboratory Animals (LRP/RAF/SOP/4051)