PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS INDIA

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13 January 2026

Sh. Rajiv Ranjan Singh alias Lalan Singh ji
Hon'ble Union Minister of Fisheries, Animal Husbandry and Dairying
Room no. 234, Ministry of Fisheries, Animal Husbandry and Dairying
Krishi Bhawan
Dr. Rajendra Prasad Road, Rajpath Area, Central Secretariat
New Delhi 110001

Subject: US Food and Drug Administration (FDA) Issues Public Warning Letter to Palamur Biosciences Highlighting Systemic Failures, Corroborating Previous Concerns Raised

Dear Hon'ble Minister Shri Lalan Singh ji:

I am writing on behalf of People for the Ethical Treatment of Animals India (PETA India) and our more than 2 million members and supporters to follow up on our letter dated 23 December 2025 requesting an urgent review of the composition and inspection practices of the Committee for the Control and Supervision of Experiments on Animals (CCSEA) in light of conflicts of interest and compromised impartiality **(Annexure 1)**. This follow-up is necessitated by an exceptionally serious international regulatory development that fundamentally alters the gravity of this matter.

On 11 December 2025, the United States Food and Drug Administration (FDA) issued a public formal warning letter[1] to Palamur Biosciences Pvt. Ltd. **(Annexure 2)** through its Center for Devices and Radiological Health following an inspection conducted by its Office of Bioresearch Monitoring Inspectorate (OBMI) Foreign Inspection Cadre in January 2025. The FDA concluded that Palamur had committed "**serious violations of Title 21, Code of Federal Regulations (CFR) Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies.**" The FDA expressly stated that these violations demonstrate "**systemic failures in study director oversight of nonclinical laboratory studies and brings into question the quality and integrity of safety data collected at your testing facility**".

Of particular relevance to animal welfare, the FDA documented: poor or absent individual veterinary records; poor record-keeping during experimental processes and unsatisfactory SOPs rendering data unreliable; lack of documented veterinary examinations prior to invasive procedures; inadequate

[1] U.S. Food and Drug Administration. *Warning letter to Palamur Biosciences Private Limited* [Internet]. Silver Spring (MD): FDA; 2025 Dec 11 [cited 2025 Dec 23]. Available from: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/palamur-biosciences-private-limited-708579-12112025

euthanasia procedures failing to ensure rapid unconsciousness and minimal distress; failure to ensure personnel clearly understand their duties; unapproved deviations from protocols that were neither detected nor documented by Palamur Biosciences' Quality Assurance Unit; and unsanitary facility conditions including dirt, debris, animal droppings and "pest harborage".

While the FDA identified multiple systemic failures at Palamur's facility, the explanations offered by the facility in its response failed to provide any substantive justification or corrective measures. The FDA further found Palamur's responses to be "inadequate," stating they **"do not provide assurance that similar violations would not occur again"** and that deficiencies yield "questionable study results". The FDA warned, **"The unreliable data raises concerns about the quality and integrity of associated premarket submissions, which may put public health and safety at risk."**

The FDA's findings substantially corroborate the concerns recorded in the detailed inspection report submitted to the CCSEA on 17 June 2025 by multi-disciplinary experts it appointed. That report recommended "**immediate regulatory action…including the removal and rehabilitation of animals in order to prevent further pain and suffering**" as well as a review of Palamur's registration and breeding license status—actions which the CCSEA has failed to implement while attempting to overshadow the report's findings through subsequent scant inspection reports by other animal experimenters.

For ease of reference, we have enclosed (**Annexure 3)** a comparative analysis between the findings of the 17 June 2025 CCSEA inspection report with the FDA 11 December 2025 Warning Letter to demonstrate the entrenched and persistent nature of core deficiencies. **The FDA's conclusions make it unequivocally clear that the deficiencies observed at Palamur are not minor procedural lapses, but deep-rooted failures affecting animal welfare, scientific validity, and public trust.**

Crucially, the FDA's findings also expose a sustained pattern of resistance and inability by Palamur Biosciences for meaningful corrective action. Despite multiple regulatory interventions, **Palamur has repeatedly responded by contesting and downplaying findings** or offering lip service, perfunctory assurances and superficial procedural revisions, failing to implement preventive or systemic reforms. Indeed, instead of improving, Palamur has acted to resist real regulatory oversight and challenge concerns raised by whistleblowers and through the 17 June 2025 report inspection findings in court.

Palamur Biosciences apparently did not learn even from its experience of the US Environmental Protection Agency publicly announcing it had stopped

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accepting studies from Palamur "**due to falsification of data discovered in numerous studies**" in May 2024, and the Canadian Pest Management Regulatory Agency taking action over similar concerns in June 2024. Compliance has been treated at best as a bare-minimum, box-ticking exercise to preserve business-as-usual operations rather than as a mandate to prevent animal suffering or ensure scientific integrity by Palamur.

The FDA's findings expose the direct consequences of conflicted regulatory oversight: animals are subjected to unnecessary pain and distress, while the scientific data generated is unreliable, non-usable, and unfit for protecting public health. By essentially allowing Palamur Biosciences to evade genuine consequences despite documented violations, CCSEA's current composition and inspection methodology are failing both animal welfare and scientific integrity. Such regulatory permissiveness not only enables cruelty to animals but also undermines India's credibility as a jurisdiction committed to rigorous, ethical, and scientifically sound research.

It is against this backdrop of demonstrated regulatory failure and international scrutiny that we respectfully draw the Ministry's attention to the notification[2] issued on 23 December 2025, whereby representatives from the Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT) on the CCSEA have been substituted. While we note the Ministry's action in notifying these changes, we submit that the revision does not address the core structural concern raised in our representation to you dated 23 December 2025 detailing the systemic dominance of active animal experimenters or those from animal testing institutions within the CCSEA's decision-making and inspection framework.

With respect to the newly appointed members:

- Dr Ruchi Singh, Scientist-F (Microbiology), is from Indian Council of Medical Research (ICMR)[3]. ICMR institutes like National Animal Resource Facility for Biomedical Research (NARFBR) in Hyderabad are engaged in animal experimentation. She replaces Dr Mukesh Kumar Gupta, one of the key inspectors who signed the 17 June 2025 inspection report relating to Palamur Biosciences Pvt. Ltd. The absence of any explanation for the removal of an inspector from this inspection creates a reasonable apprehension that the change was due to his view that animal welfare problems at Palamur are severe.

[2] Pharmabiz News Service. *DoFAHD appoints new members to CCSEA*. Pharmabiz. 2025 Dec 23. Available from: https://www.pharmabiz.com/NewsDetails.aspx?aid=183201&sid=2
[3] Singh R. Dr. Ruchi Singh [Internet]. [cited 2026 Jan 4]. Available from: http://instpath.gov.in/Dr.%20Ruchi%20Singh.pdf

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- Dr Nagendra R. Hegde[4], Scientist-H, BRIC–National Institute of Animal Biotechnology (NIAB), Hyderabad, has a portfolio that demonstrates extensive, long-term, and systematic dependence on animal experimentation and animal disease models. In substance, therefore, the representation has merely shifted from the Director of NIAB to another senior NIAB scientist, leaving intact the same conflicts of interst that underlies our concerns.

Accordingly, the recent substitutions do not resolve the deeper issue of impartiality envisaged under Section 15 of the Prevention of Cruelty to Animals Act, 1960, nor help conform to the Act's objective of prioritizing animal welfare.

We are further constrained to reiterate our serious concern regarding inspection-level conflicts of interest in the Palamur Biosciences matter.

Specifically:

- The inspections conducted post the 17th June 2025 report involved inspectors who were themselves active animal experimenters, directly undermining the lack of bias required for credible welfare assessment.
- The last inspection report dated 3 October 2025 included Dr. M Jerald Mahesh Kumar, Chief Scientist at CSIR - Centre for Cellular and Molecular Biology (CCMB). But CCMB has provided a dedicated space to Palamur Biosciences in their Atal Incubation Centre, and thus the two facilities have a business relationship."
- These concerns must be read together with the findings and directions of the Hon'ble Delhi High Court (judgment dated 16 September 2025 in W.P. (C) 9350/2025**)**, which took note of serious deficiencies and expected meaningful regulatory action—action that has yet to materialise.

Taken cumulatively, these developments suggest not isolated lapses but a **pattern of conflicted oversight**, with direct implications for enforcement credibility, animal welfare outcomes, and public confidence in the CCSEA and India's research institutions.

In light of the above, we once again respectfully request the Ministry to:

1. **Undertake an urgent review of the current composition of the CCSEA Core Committee**, and take all appropriate steps to ensure balanced representation from experts in animal welfare, bioethics, law, and non-animal scientific research.

[4] Hegde NR. Dr. Nagendra R. Hegde [Internet]. National Institute of Animal Biotechnology; [cited 2026 Jan 4]. Available from: https://www.niab.org.in/PeopleResearchNagendraHegde.aspx

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2. **Mandate periodic and surprise inspections of facilities and issue directions that CCSEA nominees and other inspectors appointed for facility inspections be independent and free of conflict of interest**, in particular, refraining from deputizing active animal experimenters or persons from animal experimenting institutes to inspect establishments engaged in animal experimentation.
3. **Establish transparent criteria for appointment and rotation of inspectors**, in line with good governance practices and the principles of the Prevention of Cruelty to Animals (PCA) Act, 1960, CPCSEA Guidelines for Laboratory Animal Facility, 2015 and other Rules and Guidelines related to the care of animals in laboratories as listed on the CCSEA website.
4. **Issue a formal cancellation of the highly irregular CCSEA 25 June 2025 Public Notice** posted on its website that has subject header stating, 'Letter of PeTA, India regarding violations of CCSEA regulations at the Animal House Facility of Palamur Biosciences Pvt. Ltd., Mahabubnagar, Telangana'[5], and ensure CCSEA sends a copy of this cancellation to all CCSEA registered facilities that received the original Public Notice.
5. **Take immediate action on the recommendations made in the 17 June 2025 inspection report** relating to Palamur Biosciences, **which now stand independently corroborated by the FDA's Warning Letter dated 11 December 2025**.

We submit this follow-up in the spirit of constructive engagement and in furtherance of the Ministry's statutory duty to ensure that animals are not subjected to unnecessary pain or suffering before, during, or after experimentation, and we would be grateful if this request could be considered urgently and if we may be informed of the steps being taken by the Ministry to ensure impartial and credible oversight of animal experimentation in India.

I can be reached +919958840994 or via email on aaggarwal@petaindia.org. Thank you for your urgent attention and consideration. We look forward to the Ministry's prompt action.

Sincerely,

Dr. Anjana Aggarwal
Scientist and Research Policy Advisor

[5] Committee for Control and Supervision of Experiments on Animals. Public Notice: Letter of PETA India regarding violations of CCSEA regulations at the Animal House Facility of Palamur Biosciences Pvt. Ltd., Mahabubnagar, Telangana [Internet]. 25 Jun 2025 [cited 2025 Nov 9]. Available from: https://ccsea.gov.in/WriteReadData/LnPdf/PublicNotice_LetterofPeTAIndia.pdf

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Enclosures:

1. Annexure 1: Reference Letter to the Minister dated 23 December 2025
2. Annexure 2: FDA warning letter to the Palamur Biosciences Pvt. Ltd.
3. Annexure 3: Comparative analysis between the findings of the 17 June 2025 CCSEA inspection report with the FDA's 11 December 2025 Warning Letter

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Annexure 1:

Reference Letter to the Minister dated 23 December 2025

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23 December 2025

Sh. Rajiv Ranjan Singh alias Lalan Singh ji
Hon'ble Union Minister of Fisheries, Animal Husbandry and Dairying
Room no. 234, Ministry of Fisheries, Animal Husbandry and Dairying
Krishi Bhawan
Dr. Rajendra Prasad Road, Rajpath Area, Central Secretariat
New Delhi 110001

Subject: Request for urgent review of the composition and inspection practices of the Committee for the Control and Supervision of Experiments on Animals (CCSEA) in light of conflicts of interest and compromised impartiality

Dear Hon'ble Minister Shri Lalan Singh ji:

I am writing on behalf of People for the Ethical Treatment of Animals India (PETA India) and our more than 2 million members and supporters to respectfully express grave concerns regarding evident conflicts of interest in the current composition and functioning of the Committee for the Control and Supervision of Experiments on Animals (CCSEA) that appear to translate to biased oversight, weak enforcement, and the perpetuation of cruelty to animals.

In light of our serious concerns described below, we respectfully request the Ministry to:

1. **Undertake an urgent review of the current composition of the CCSEA Core Committee**, and take all appropriate steps to ensure balanced representation from experts in animal welfare, bioethics, law, and non-animal scientific research.
2. **Mandate periodic and surprise inspections of facilities and issue directions that CCSEA nominees and other inspectors appointed for facility inspections be independent and free of conflict of interest**, in particular, refraining from deputizing active animal experimenters to inspect establishments engaged in animal experimentation.
3. **Establish transparent criteria for appointment and rotation of inspectors**, in line with good governance practices and the principles of the Prevention of Cruelty to Animals (PCA) Act, 1960, CPCSEA Guidelines for Laboratory Animal Facility, 2015 and other Rules and Guidelines related to the care of animals in laboratories as listed on the CCSEA website.

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4. **Issue a formal cancellation of the highly irregular CCSEA 25 June 2025 Public Notice** posted on its website that has subject header stating, 'Letter of PeTA, India regarding violations of CCSEA regulations at the Animal House Facility of Palamur Biosciences Pvt. Ltd., Mahabubnagar, Telangana'[1], and send a copy of this cancellation to all CCSEA registered facilities that received the original Public Notice.

CCSEA Core Committee Heavily Composed of Animal Experimenters

CCSEA is statutorily mandated under the PCA Act, 1960, to ensure the ethical treatment of animals used for scientific and educational purposes; however, its present structure and operational practices have raised serious questions about impartiality and credibility that undermine its intended purpose.

There is currently a significant overrepresentation of individuals who are active proponents or practitioners of animal experimentation within the CCSEA's Core Committee (Appendix A), which means that animal experimenters are expected to police other animal experimenters. This is highly problematic because there are a whole host of scenarios that present conflicts of interests:

- Animal experimenters heavily rely on other animal experimenters for scientific collaborations, making it less likely one will find another in violation of applicable regulations in order to preserve collaboration opportunities;
- Animal experimenters may extend professional courtesies (e.g., overlooking a regulatory violation) to other animal experimenters practicing in the same field to maintain rapport and goodwill amongst colleagues;
- Animal experimenters may have strong hesitations to penalize fellow animal experimenters for a regulatory violation when the latter could subsequently be named to sit on a future CCSEA Core Committee with oversight over the former;
- Animal experimenters rely largely on grant funding to pursue their work and assessing regulatory violations against fellow animal experimenters who sit on grant-making bodies may decrease odds of future grants being awarded to the former; and,
- Animal experimenters have vested career and business interests in maintaining the status quo that minimizes citations of regulatory violations and negative media publicity so as to protect and preserve

[1] Committee for Control and Supervision of Experiments on Animals. Public Notice: Letter of PETA India regarding violations of CCSEA regulations at the Animal House Facility of Palamur Biosciences Pvt. Ltd., Mahabubnagar, Telangana [Internet]. 25 Jun 2025 [cited 2025 Nov 9]. Available from: https://ccsea.gov.in/WriteReadData/LnPdf/PublicNotice_LetterofPeTAIndia.pdf

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the collective enterprise of animal experimentation from heightened public and political scrutiny that could undermine the justification for the enterprise's continuation.

CCSEA Appoints Animal Experimenters as Animal Facility Inspectors

CCSEA has discretion in who it appoints to conduct inspections of animal facilities under its purview. **CCSEA regularly appoints animal experimenters as inspectors in cases involving allegations of cruelty to animals and regulatory non-compliance, which introduces significant bias and undermines the credibility of the inspections themselves.**

In the inspection report[2] dated 24 July 2025 and a separate inspection report[3] dated 3 October 2025 concerning Palamur Biosciences Pvt Ltd (CCSEA Registration Number: 1312/PO/RcBiBt-S/RcBiBt-L/09/CPCSEA) (hereinafter, 'the Company'), located at Karvena (Village), Bhoothpur (Mandal), Mahabubnagar-District- 509001 Telangana, CCSEA-appointed inspectors, who are also animal experimenters, essentially gave 'clean-chits' to the Company despite a prior, highly detailed inspection report submitted to CCSEA on 17 June 2025 **(Appendix B)** that found a '*systemic and ongoing disregard for regulatory compliance, ethical responsibility, and animal welfare*' at the Company and that called for the ***'[i]mmediate … removal and rehabilitation of animals … as well as a review of [the Company's] registration and breeding license status***'[4].

Notably, instead of acting on the recommendations and strong rebuke of the Company's regulatory violations in the 17 June 2025 inspection report, CCSEA apparently sought to undermine the legitimacy of the 17 June 2025 *multi-disciplinary inspection team*—composed of Dr Mukesh Kumar Gupta, CCSEA Member and Director of Indian Council for Medical Research-National Animal Resource Facility for Biomedical Research; Dr Vivek Tyagi, Senior Consultant CCSEA; a member of the Animal Welfare Board of India; two nominees of the Institutional Animal Ethics Committee; and Alokparna Sengupta, Managing Director of Humane World for Animals—by apparently manufacturing 'clean-chit' inspections of the Company by animal experimenters.

Prior to the 24 July 2025 inspection, PETA India had raised concern against Dr. Ramachandra S.G., Chief Research Scientist, Indian Institute of Science

[2] Ramachandran inspection report on Palamur Biosciences Pvt. Ltd. [Internet]. 24 Jul 2025 [cited 2025 Nov 27]. Available from: https://www.petaindia.com/wp-content/uploads/2025/11/2025-07-24-ramachandran-report.pdf
[3] Local Commissioner report on Palamur Biosciences Pvt. Ltd. [Internet]. 03 Oct 2025 [cited 2025 Nov 27]. Available from: https://www.petaindia.com/wp-content/uploads/2025/11/2025-10-03-local-commissioner-report.pdf
[4] People for the Ethical Treatment of Animals (India). *Palamur Inspection Report* 17 Jun 2025 [cited 2025 Nov 9]. Available from: https://www.petaindia.com/wp-content/uploads/2025/06/Palamur-Inspection-Report.pdf

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(IISC), who is also a CCSEA Core Committee member, being part of it. Specifically, PETA India raised that **former union minister Maneka Gandhi, who is a former Chairperson of CPCSEA (now called CCSEA), had accused IISC in 2022 of killing huge numbers of animals[5] and engaging in other cruelty.** But CCSEA went to great lengths to ensure the inspector is none other than Dr. Ramachandra S.G.

CCSEA Appears to Orchestrate a Cover-Up of Abuses at the Company

Furthermore, in a highly irregular move, again instead of acting on the recommendations of the 17 June 2025 report, CCSEA threatened PETA India with legal action if PETA India failed to reveal who provided it with a copy of the 17 June 2025 inspection report and issued a 'Public Notice'[6] on its website—which is still currently posted live—asking CCSEA registration holders to disregard any communication from PETA India regarding the Company. However, in communications, PETA India was merely supporting the 17 June 2025 official inspection report.

Systemic Gaps in CCSEA's Inspection Framework Further Exacerbate Conflicts of Interest

There are several structural deficiencies in CCSEA's inspection and oversight framework that further compromise impartiality and allow regulatory violations to persist unchecked:

• There is a lack of sufficient, serious and thorough inspections by CCSEA or by independent inspectors/animal welfare experts with no publicly documented routine system of surprise inspections. This structural gap results in inadequate regulatory scrutiny and allows establishments to hide wrongdoing and continue operations without meaningful oversight (e.g., CCSEA did not acknowledge the abuse and neglect of animals at Palamur Biosciences Pvt Ltd until the submission of the 17 June 2025 inspection report, which only occurred in response to PETA India's 10 June 2025 complaint based on alarming video footage, photographs and testimonials from Palamur Biosciences Pvt Ltd insiders [7]).

• The only mandatory annual inspection is conducted by the CCSEA Nominee to the Institutional Animal Ethics Committee (IAEC), but this inspection is announced and the nominee is *paid by the very facility they are expected to objectively assess*. This financial relationship can create an

[5] The New Indian Express. Animal cruelty in central animal facility: Maneka Gandhi to IISc head. 2022 Sep 24 [cited 2025 Dec 05]. Available from: https://www.newindianexpress.com/cities/bengaluru/2022/Sep/24/animal-cruelty-in-central-animal-facility-manekagandhito-iisc-head-2501332.html

[6] Committee for Control and Supervision of Experiments on Animals. Public Notice: Letter of PETA India regarding violations of CCSEA regulations at the Animal House Facility of Palamur Biosciences Pvt. Ltd., Mahabubnagar, Telangana [Internet]. 25 Jun 2025 [cited 2025 Nov 9]. Available from: https://ccsea.gov.in/WriteReadData/LnPdf/PublicNotice_LetterofPeTAIndia.pdf

[7] People for the Ethical Treatment of Animals (PETA) India. *Complaints to CCSEA, CDSCO, NGCMA regarding Palamur Biosciences* [Internet]. 2025 Oct 4 [cited 2025 Dec 22]. Available from: https://www.petaindia.com/wp-content/uploads/2025/06/2025-10-04-complaints-to-ccsea-cdsco-ngcma-re-palamur-biosciences-1.pdf

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inherent conflict of interest and run contrary to universally accepted principles of independent regulatory monitoring.

• The prescribed proforma[8] for these annual IAEC inspections is inadequate and lacks detailed and specific animal-welfare criteria or experimentation oversight, encouraging superficial procedural formalities and inspections that are difficult to compare rather than a substantive evaluation of animal housing, management, or well-being.

Reconstitution of CCSEA Core Committee and Inspectors is Needed

The aforementioned and enclosed conflicts of interest by CCSEA undermine the principles of administrative fairness, transparency, and justice, eroding the public's confidence in the government's mechanisms for ensuring humane treatment of animals. They also stand contrary to the intent of the PCA Act 1960, which envisages oversight by a body that is guided by the highest ethical standards.

A reconstitution of the CCSEA Core Committee and the committee's appointed inspectors to reflect true independence and diversity of animal welfare expertise will help restore public trust and ensure credible regulatory enforcement.

We would be grateful if this request could be considered urgently, and if we may be informed of the steps being taken by the Ministry to ensure impartial oversight of animal experimentation in India.

You may reach me at +919958840994 or email to me at aaggarwal@petaindia.org. We look forward to your prompt response.

Sincerely,

Dr. Anjana Aggarwal
Scientist and Research Policy Advisor

Enclosures:
Appendix A: Analysis of CCSEA Core Committee Members
Appendix B: 17 June 2025 Inspection Report

[8] Committee for the Control and Supervision of Experiments on Animals. *Compendium of CPCSEA guidelines and regulations.* [Internet]. [cited 2025 Nov 27]. p. 173–. Available from: https://ccsea.gov.in/WriteReadData/userfiles/file/Compendium%20of%20CPCSEA.pdf

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Appendix A: Analysis of CCSEA Core Committee Members

S.No.	Member Name	Institute	Relation to Animal Testing/Labs
1.	Dr. Muthukumarasamy B, IAS	Joint Secretary, AWBI	NA
2.	Representative from AWBI (name not revealed)	AWBI	
3.	Dr. Rajendra Gulabrao Bambal	Secretary (Addl. Charge), Veterinary Council of India	Significant amount of animal experimentation on livestock 'productivity'[9].
4.	Dr. S. Kavimani	Professor & HOD, Department of Pharmacology, Mother Theresa Postgraduate & Research, Institute of Health Sciences, Puducherry	Active animal experimenter (e.g., toxicity tests) and has published various experiments on mice[10].
5.	Dr. A. Vishala	Joint Drugs Controller, Central Drugs Standards Control Organization, New Delhi	Associated with CDSCO that routinely accepts, reviews, and relies on animal-derived data for decision-making.
6.	Chairman or his representative (Name not revealed)	National Medical Commission (NMC)	Current regulations of NMC continue to include animal experimentation as an integral part of the curriculum for certain postgraduate medical courses, specifically in Physiology and Pharmacology.
7.	Prof. Rana Pratap Singh, Member	Jawaharlal Nehru University (JNU), School of Life Sciences, New Delhi	JNU's Centre for Laboratory Animal Research (CLAR) conducts CCSEA-registered animal experimentation for life sciences, likely involving rodents for genetic and biomedical experiments.
8.	Dr. Mukesh Kumar Gupta, Member	ICMR - National Animal Resource	NARFBR is a CCSEA-registered breeder and

[9] Bambal, Rajendra Gulabrao. "Scientific Contributions." *ResearchGate*. ResearchGate, n.d., www.researchgate.net/scientific-contributions/Rajendra-Gulabrao-Bambal-2084502230. Accessed 10 Nov. 2025.
[10] Kavimani, S. "S. Kavimani | Professor (Full) | M.Pharm., PhD." *ResearchGate*, ResearchGate, n.d., www.researchgate.net/profile/S-Kavimani. Accessed 10 Nov. 2025.

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		Facility for Biomedical Research (NARFBR), Hyderabad	supplier of specific pathogen free animals (e.g., mice, rats, rabbits, dogs, goats, pigs, horses, monkeys) for laboratory biomedical experiments.
9.	Dr. Karthikeyan Vasudevan, Chief Scientist	Laboratory for the Conservation of Endangered Species (LaCONES), Centre for Cellular and Molecular Biology (CCMB), Hyderabad, Telangana	LaCONES routinely conducts reproductive / biotechnology intervention experiments on animals, including wildlife species and rodents.
10.	Dr. Raghavendra Bhatta, Deputy Director General (AS)	Indian Council of Agricultural Research (ICAR), New Delhi	ICAR's mandate explicitly includes conducting, funding, and promoting experiments on animals.
11.	Dr. G Taru Sharma, Member	National Institute of Animal Biotechnology (NIAB), Hyderabad	NIAB relies heavily on invasive animal experiments.
12	Dr. Asmita Gajbhiye	Professor and Dean, School of Engineering and Technology, Dr. Harisingh Gour University, Sagar, Madhya Pradesh	Dr. Harisingh Gour University, Sagar, Madhya Pradesh conducts animal-based teaching and experiments across its Zoology, Pharmacy, Biotechnology, and Life Sciences departments, making it an active user of animals in laboratories.
13.	Prof. Dr. Arvind Dasharath Ingle	Scientific Officer 'H' and Officer-in-Charge, Laboratory Animal Facility & Histopathology, Tata Memorial Centre, Advanced Centre for Treatment Research & Education in	Prof. Dr. Arvind Dasharath Ingle uses animals in various experiments at ACTREC[11].

[11] Ingle, Arvind. "Dr. Arvind Ingle." *ACTREC*https://actrec.gov.in/dr-arvind-ingle . Accessed 10 Nov. 2025.

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS INDIA

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		Cancer (ACTREC), Mumbai, Maharashtra	
14.	Dr. Subeer S. Majumdar, Member	Gujarat Biotechnology University, Gandhinagar	Operates a CCSEA-registered animal facility for biotechnology experiments, focusing on transgenic and genetic models[12].
15.	Dr. Ramachandra S.G., Member	Indian Institute of Science (IISc), Central Animal Facility, Bangalore	IISc's Central Animal Facility is CCSEA-registered, and uses animals for basic and applied experiments across disciplines like neuroscience and pharmacology[13].
16.	Dr. Suresh Pothani, Member	ICMR-NARFBR, Hyderabad (Retired)	Previously directed NARFBR, where he supervised animal breeding and preclinical testing, with direct involvement in experimentation on animals. [14]
17.	Dr. R. Gopinath, Member	All India Institute of Medical Sciences (AIIMS), New Delhi	AIIMS's Central Medical and Imaging Experimentation (CMIE) Animal Testing Centre uses animals including rats, mice, rabbits, guinea pigs, and hamsters for pharmacology and physiology experiments[15].
18.	Dr. Pradeep Bhatu Patil, Member	ICMR-National Institute of Nutrition (NIN), Hyderabad	NIN's CCSEA-registered animal facility breeds, supplies, and uses animals for nutrition and dietary experiments, making it directly involved in extensive animal experimentation. [16]
19.	Dr. SK Dutta	Joint Commissioner, DAHD	

[12] Majumdar, Subeer S. "Dr Subeer S. Majumdar." *NII Former Faculty*, National Institute of Immunology. https://www.nii.res.in/en/former-faculty/dr-subeer-s-majumdar Accessed 10 Nov. 2025.
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Appendix B:
17 June 2025 Inspection Report

Report on the Inspection of Palamur Biosciences Private Limited

Submitted on 17th June 2025

Disclaimer

This report has been prepared by the inspection team tasked with conducting a fact-based verification into allegations of cruelty to animals and serious non-compliance with regulatory requirements at Palamur Biosciences Pvt. Ltd. (PBPL). The inspection was undertaken with the objective of assessing the facility's adherence to applicable animal welfare laws, guidelines, and standards.

The observations and findings recorded herein are focused on areas of concern that warrant immediate attention and remedial action. While the report highlights key gaps and deficiencies observed during the inspection, it is not intended to serve as an exhaustive documentation of all operational procedures or standard practices at PBPL.

This report represents the considered findings of the inspection team, based on direct observations, review of documents, information made available by PBPL representatives, and other relevant evidence gathered during the course of the visit. It is submitted to the CCSEA for further examination and appropriate action under the relevant regulatory provisions.

I. Executive Summary

The inspection of Palamur Biosciences Pvt. Ltd. (PBPL) on June 11, 2025 and June 12, 2025, conducted by a multidisciplinary team comprising members from the Committee for the Control and Supervision of Experiments on Animals (CCSEA), the Animal Welfare Board of India (AWBI), the Institutional Animal Ethics Committee (IAEC), and Humane World for Animals India Foundation, was initiated to verify recent allegations of animal welfare violations involving dogs, pigs, and, monkeys used in research during the period 2021–2023.

PBPL currently houses a substantial number of animals: approximately 1,169 dogs, along with monkeys, pigs (including minipigs and mixed breeds), sheep, cattle, and an undetermined number of rodents and lagomorphs (rabbits). The overall population of dogs far exceeds CCSEA-approved limits, with multiple species present without adequate disclosure or accurate record-keeping. Critical documentation - including consolidated animal inventories, veterinary treatment records, and breeding logs - was consistently absent, incomplete, or untraceable.

The inspection revealed serious and widespread non-compliance with CCSEA regulations. Key welfare violations included overcrowded and barren kennels, lack of environmental enrichment, feeding practices not aligned with the animals' physiological needs and body weight requirements, untrained and rough handling practices, and an alarming absence of protocols for pain management, sedation, and euthanasia. Veterinary infrastructure was critically inadequate, with poor medical coverage, minimal drug availability, and no functioning isolation or quarantine facilities.

Particularly disturbing were the euthanasia practices observed: beagle dogs were euthanised using thiopentone sodium without prior sedation, and monkeys subjected to invasive surgical procedures involving implantation and daily wound care were physically restrained using gloves, with only analgesics administered post-procedure and dressing, and no sedatives provided. There was no protocol in place to address anxiety, fear, or psychological distress in animals—highlighting a grave neglect of mental welfare, and a veterinary protocol grossly failing to meet even the minimum required standards for the prevention of unnecessary suffering.

Furthermore, deliberate obfuscation was evident in PBPL's failure to provide CCTV footage from critical areas and in the non-disclosure of certain species during the inspection. Inconsistencies between reported study approvals and the actual number of animals on-site strongly suggest potential regulatory breaches.

The inspection team concluded that many of the allegations raised by PETA India's whistle-blower—including overcrowding, veterinary neglect, inappropriate handling, and euthanasia violations—were substantiated or could not be conclusively refuted due to the absence of required documentation.

Overall, the findings reflect a systemic and ongoing disregard for regulatory compliance, ethical responsibility, and animal welfare. Immediate regulatory action is warranted, including the removal and rehabilitation of animals in order to prevent further unnecessary pain and suffering, as well as a review of PBPL's registration and breeding licence status.

II. Introduction

1. **Date of Inspection:** 11th and 12th June 2025

2. **Time of Inspection:** On-site from 2:30 PM to 11:30 PM on 11th June; remote inspection from 10:00 AM to 12:00 PM on 12th June

3. **Name of Institution:** Palamur Biosciences Pvt. Ltd.

4. **Type of Institution:** Private

5. **Location:** Karvina, Madigattla Village, Bhoothpur Mandal, Mahabubnagar 509 382, Telangana, India

6. **Purpose of Inspection:**
   To verify complaints regarding the alleged abuse and neglect of dogs, pigs, and monkeys used in research and testing at Palamur Biosciences Pvt. Ltd. (*hereinafter referred to as PBPL*), Mahabubnagar, Telangana, during the period 2021–2023. The inspection also aimed to assess the overall conditions and practices related to animal care and use at the facility.

7. **Inspectors:**
   - Dr. Mukesh Kumar Gupta – Member, CCSEA & Director, ICMR-NARFBR, Hyderabad
   - Dr. Manilal Valliyate – Member, AWBI
   - Dr. Vivek Tyagi – Senior Consultant, CCSEA
   - Dr. B.D.P. Kala Kumar – Main Nominee, IAEC
   - Shri A. Madhava Rao – Socially Aware Nominee, IAEC
   - Ms. Alokparna Sengupta – Managing Director, Humane World for Animals India Foundation (formerly known as Humane Society International/India)

III. Animal Use Details

1. **Species Used in Experiments:**
The facility reportedly uses dogs, pigs (minipigs and mixed breed pigs), sheep, cattle, monkeys, and other species for experimental purposes.

Species-wise Distribution of Animals Housed at the Time of Inspection
It is physically not feasible for the inspection team to individually count the animals or determine their sex and age in the absence of any records provided by the facility. However, this exercise was carried out for the dogs and cattle at the housing facilities that were shown to the inspectors, though the numbers observed may not accurately represent the total number of dogs being housed or used by the facility.

Detail of animals	Species	Number	Sex	Age	Remarks
Monkeys	*Macaca mulata*	No record	No record	No record	Not counted by inspectors.
Pigs	*Sus scrofa domestica* and mixed species	No record	No record	No record	Not counted by inspectors.
Dogs	*Canis lupus familiaris*	No record	No record	No record	1169 numbers based on the headcount conducted by the inspectors at the facilities that were shown.
Cattle	*Bos Indicus*	No record	No record	No record	12 numbers based on head count.
Sheep	*Ovis aries*	No record	No record	No record	Not counted by inspectors.
Rodents [Mice, rats, rabbits]	No records shown, and no animals were presented for inspection	-	-	-	No inspection was carried out, as it was not a part of the mandate given to the inspection team by CCSEA.

PBPL failed to provide any documentation detailing the number, age, sex, or species-wise inventory of animals held or used at the facility, despite repeated requests. Although staff acknowledged the existence of an internal Excel spreadsheet containing this information, it was never shared with the inspection team.

Headcount and Observations from the Inspection

Facility	Facility Name	Number of kennels/ cages/ enclosures	No of animals	Remarks
Dogs				Headcount done by inspectors
Breeding Facilities	Module - A	40	85	
	Module - B		200	30 adults + 170 pups
	Module - C		122	36 adults + 86 pups
	Module - D	36	95	
	Maternity (MAT-1)	44	132	Pups 2-4 months
	Maternity (MAT- II)	45	126	Pups above 4 months
	Stock	42	61	Pups above 5 months
Experimentation Facilities	Experiment Room 2		32	
	Experiment Room 3		39	Stock animals accommodated without prior screening
	Experiment Room 6		40	
	Experiment Room 7		62	
	Experiment Room 10		40	
	Experiment Room 11		16	
	Experiment Room 13		46	Stock animals accommodated without Prior screening
	Rehabilitation		73	62 male + 11 female
		Total	**1169**	**594 adults + 575 pups**
Minipigs			14	9 male + 5 female
Non-Humane Primate			17	13 male + 4 female
Mixed-Breed Pig			13	As informed verbally
Sheep			7	As informed verbally
Cattle			12	Headcount done
Rodents & Others			Unknown	
		Grand Total	**1232 +**	Unknown number of rodents and others.

2. **Non-compliances in Animal Use**
The headcount and placement of dogs housed at PBPL indicate that the facility is exceeding the number approved by CCSEA, in direct violation of regulatory limits, which is 1000 dogs. This overpopulation appears to stem from breeding activities surpassing the number of animals required for ongoing experiments. As a result, two rooms—originally designated for experimentation and located in close proximity to active experimental areas—were repurposed as stock rooms to accommodate the surplus animals. Notably, this was done without screening the dogs for infectious diseases. Veterinarians at the facility stated that the rooms would be fumigated and sterilised before being returned to experimental use; however, even if this is outlined in the organisation's SOPs, reliance on such reactive measures raises concerns regarding the robustness of biosafety protocols.

3. **Number of Animals Currently Under Rehabilitation**
At the time of inspection, 73 dogs-comprising 62 males and 11 females-were reported to be under rehabilitation. This information was provided verbally, with no supporting written documentation shared by the facility. However, a headcount conducted by the inspectors confirmed the reported total.

It was observed that the so-called "rehabilitation area" appeared to be a makeshift arrangement, with a fresh paper label affixed to the door designating it as such. The space itself was evidently an experimental room repurposed as a rehabilitation unit, with no meaningful changes made to accommodate the specific needs of animals undergoing recovery. The environmental conditions, infrastructure, routine practices, and personnel remained consistent with those of a laboratory setting, raising serious concerns about the adequacy, appropriateness and sincerity of the rehabilitation process.

4. **Number of Animals Reused for Experimentation**
The inspection team was informed that animals across all species are reused in multiple experiments, including pharmacokinetic and toxicological studies. In the case of dogs and minipigs, it was claimed that a three-year usage period is followed, with intermittent "washout period" of one month between experimental uses. However, no written policy documents, institutional protocols, or Standard Operating Procedures (SOPs) were provided to substantiate this claim. Practising a one-month "washout period" is a violation of CCSEA guidelines for reuse/rehabilitation of large animals post experimentation (2020), which mandates a minimum of three months as a "washout period".

It was conveyed that pharmacokinetic studies generally involve repeated use of the same animal, whereas toxicological studies are usually conducted only once per animal. The CCSEA guidelines for reuse/rehabilitation of large animals post experimentation (2020) mandate that animals showing liver or kidney impairment, within the three-year period, cannot be reused, and the detailed health status of all such animals shall be maintained in a prescribed format. However, in the absence of accessible records, there was no way to independently verify these practices.

IV. Compliance to CCSEA Mandates

Sl. No.	Particulars	Yes/ No	Remarks
1.	Registration with CPCSEA for experimentation	Yes	
2.	Registration with CPCSEA for breeding animals for experimentation	Yes	
3.	Whether 3R principles followed	No	Reduction in animal use is a principle overseen by the CCSEA during the review and approval of research proposals. However, PBPL failed to demonstrate how many times individual animals were reused—a practice that requires specific approval from the CCSEA. The absence of such consolidated records strongly suggests non-compliance with regulatory requirements. As for the principle of Refinement, there appears to be a complete disregard. Despite conducting procedures that are invasive or likely to cause physical and psychological distress, the clinical examination areas adjacent to the experimentation rooms were found to be unequipped with basic medical kits. Furthermore, the medical inventory lacked essential sedatives, analgesics, and anaesthetics—key components for preventing unnecessary pain and suffering in animals. No consolidated treatment records were maintained to document either pain recognition or pain management.
4.	Housing facilities for animals being bred	No	During the inspection of the dog breeding facilities at PBPL, several serious violations of housing and welfare standards were noted.

			None of the dogs in the breeding modules were provided with any form of bedding and were left to lie directly on slippery tiled floors—an inappropriate and uncomfortable surface that fails to meet even the most basic animal welfare requirements. No environmental enrichment was provided, except few plastic bones—there were no toys, stimulation objects, or opportunities for social interaction. According to staff, the dogs were only let out of their cages during cleaning, indicating a highly restrictive and unstimulating environment with extremely limited chances for exercise or socialisation. The constant noise from continuous barking created an environment with dangerously high noise levels, indicative of widespread stress and discomfort among the animals. Alarmingly, the facility manager was unable to provide the exact number of dogs housed in the breeding section, and no records were available for verification. The kennels in the dog breeding section were generally dirty, soiled with faeces, and poorly maintained. The overall environment of the dog breeding units was uninviting and clearly neglected, reflecting a troubling disregard for the basic care, hygiene, and welfare needs of the animals. Hygrometers installed in the breeding areas showed excessively high relative humidity levels, ranging from 80% to 97%, which can pose serious health risks to the animals. The designated socialisation area for dogs measured approximately 550 square metres, was barren,

			and had a hard concrete surface. Given that the facility houses over 1,000 dogs, each individual may have to wait weeks or even months for a single opportunity to access this limited space—rendering it functionally ineffective in promoting socialisation or improving welfare. In summary, the breeding modules for dogs at PBPL were found to be uncomfortable, poorly enriched, inadequately managed, and not aligned with the minimum standards of care expected for breeding animals.
5.	Housing facilities for animals being experimented upon	No	During the inspection of the experimental housing areas at PBPL, several serious concerns were identified regarding housing conditions, animal allocation, and the absence of species-appropriate enrichment. PBPL housed a range of animals—including dogs, monkeys, minipigs, pigs, and sheep—but all were confined exclusively to cages, with no access to open or enriched environments even when they were housed for more than three months, sometimes exceeding nine months. While some dogs and monkeys were housed in same-sex pairs, these arrangements are insufficient to support the natural social behaviours characteristic of these species. Critically, there were no dedicated outdoor enclosures or exercise facilities for non-human primates. This deprived the monkeys of any opportunity for natural movement, physical exercise, or cognitive stimulation. The lack of outdoor access and meaningful enrichment across species poses a significant risk to both the psychological welfare and behavioural health of the animals in PBPL's care.

			Environmental enrichment across all animal housing areas was grossly inadequate. In the experimental rooms for dogs, a few plastic bones were loosely scattered in the corridors. These rigid and repetitive items lacked the novelty or functionality to effectively engage the animals. No other enrichment tools or activities were present. Similarly, only a few minipigs were provided with enrichment in the form of cut PVC pipe sections—simple items that failed to sustain their interest or encourage exploratory behaviour. In the monkey enclosures, circular rings were suspended as the only form of enrichment. However, these minimal features were clearly insufficient to meet the cognitive and physical needs of the primates, particularly given their confinement to small cages, either alone or in same-sex pairs. **Dogs:** The dog housing units in the experimental section were equipped with artificial lighting and temperature-controlled environments; however, there was a complete absence of meaningful environmental enrichment. Plastic bones were haphazardly placed in the corridors but offered no meaningful engagement or stimulation for the animals. Several dogs from the breeding stock were found housed in two experimental facilities due to insufficient space in the designated breeding area—highlighting poor planning and inadequate resource management. Critically, these animals had not been screened for disease conditions prior to relocation, despite such screening being a mandatory prerequisite before introducing animals into experimental zones. This oversight raises serious concerns regarding contamination risks and compromised sterilisation

			standards. Additionally, some dogs were reportedly transferred for experimental procedures without visible tags or identifiers, making it impossible to trace individual histories or monitor their use—constituting a serious violation of standard compliance protocols. **Minipigs:** The housing for minipigs featured polymer flooring with rectangular drainage openings, which are unsuitable for 24 X 7 housing of cloven-footed animals to stand or lie down comfortably. No meaningful environmental enrichment was provided. Although it was unclear whether these pigs were actively being used for experimental procedures, facility staff informed the inspection team that they had been imported from Denmark. A few minipigs were offered minimal enrichment in the form of cut PVC pipe sections, including L-shaped bends. However, these were significantly undersized relative to the pigs' body dimensions, and the design posed a clear risk of choking or injury, as the openings were small enough that animals could potentially attempt to insert their heads. This highlights a lack of considered design and a failure to meet even the most basic behavioural and welfare needs of the animals. **Pigs (White Yorkshire Mixed Breeds):** These animals were not initially disclosed to the inspection team, despite repeated inquiries. Their presence came to light only incidentally during a meeting, when scientists—while discussing ongoing cardiology-related studies such as pacemaker development—unintentionally acknowledged their use. The pigs were housed in enclosures similar in design to those used for dogs, albeit larger

			in size. They were kept in isolated conditions on polymer flooring with drainage openings, which is inappropriate for 24 X 7 housing of cloven hooves and overall physiology. Furthermore, the absence of species-specific environmental enrichment highlighted a broader disregard for basic welfare standards. **Sheep:** Contrary to the facility's initial claim that no sheep were present, seven sheep were discovered by the inspection team in the experimental section during a visit to the mixed-breed pigs. This unreported presence reflects a serious disregard for regulatory compliance and a failure to meet the basic norms prescribed by CCSEA. Each sheep was individually caged without any form of environmental enrichment. The complete absence of social interaction or sensory stimulation raised significant concerns about their welfare. They were kept on polymer flooring with drainage openings, which is inappropriate for 24 X 7 housing of cloven hooves and overall physiology. **Monkeys:** The enclosures housing the monkeys offered little room for natural movement or social interaction. There were no dedicated outdoor enclosures or exercise facilities. The narrow metal platforms inside the cage made it difficult for the animals to sit or lie down comfortably, raising serious concerns about their physical comfort and overall welfare. The only form of enrichment observed was a single coloured ring suspended in each enclosure—an effort that proved grossly inadequate, failing to provide any meaningful cognitive stimulation or physical engagement.

			Cattle Twelve cows were housed in a makeshift cattle shed with minimal infrastructure and inadequate protection from the elements. Continuous rainfall had led to water accumulation in parts of the shed, creating damp and unsanitary conditions.
6.	Housing facilities for animals being rehabilitated	No	**Dogs:** The rehabilitation facility for dogs was found to be a small, corner room located on the first floor of the building. It was observed that the so-called "rehabilitation area" appeared to be a makeshift arrangement, with a fresh paper label affixed to the door designating it as such. The room was evidently an experimental space that had been repurposed, with no meaningful changes made to support the functional and welfare needs of animals in recovery. The environment was entirely artificial, with no access to natural light and fully temperature-controlled conditions. The flooring consisted of hard perforated polymer flooring with integrated drainage, which may cause discomfort, offering no physical comfort for the animals to stand, sit, or lie down for long periods. Critically, there was no provision for socialisation, environmental enrichment, or access to outdoor spaces—elements essential for the physical and psychological recovery of rehabilitating animals. The facility, as observed, fell significantly short of providing a conducive, humane, and restorative environment—undermining the very essence of what true rehabilitation should represent.
7.	Identification of animals	Yes	Dogs at the breeding centre were reported to be microchipped and tagged with neck chains; pigs and

			sheep were reported to be tagged with RFID devices, while monkeys were reported to be microchipped.
8.	General condition of animals observed	No	Dogs in poor body condition, including several exhibiting cherry eye, were observed at the breeding modules. However, due to the absence of consolidated medical records or documentation, there was no evidence of any treatment history or supportive interventions provided for these animals. General body condition of minipigs appeared poor. However, due to absence of medical records on-site, the health status of minipigs could not be ascertained. The body condition score of the cows was generally poor, with most animals appearing underweight and below the average standard.
9.	Trained staff/handlers	No	A serious welfare concern was observed when an animal handler lifted a heavy dog by the scruff and used a wiper to move the animal—an act carried out openly in front of the inspection team. The casual manner in which this was done suggests that such rough handling is a routine and accepted practice at PBPL. These actions are inappropriate and raise grave concerns about staff training, supervision, and basic regard for animal welfare. While a few dogs appeared fearful, most seemed relatively at ease around humans, indicating inconsistent and largely unmonitored handling practices across the facility.
10.	Restraint	No	All dogs at the facility were housed in individual cages with no visible form of physical restraint within the enclosures. However, they were not provided with any outdoor access or designated free time. While facility staff claimed

			that animals were let out during cleaning, a review of CCTV footage did not show dogs being allowed out for play or exercise, raising doubts about the accuracy of these claims. During cleaning, nursing mothers and puppies were reportedly transferred to crates, some of which were found to be damaged—posing both hygiene and injury risks to the animals. Of particular concern was the procedure followed during euthanasia. The veterinarian responsible openly stated that sedatives were not used prior to administering thiopentone sodium to dogs. Instead, the dogs were manually restrained before injection. This approach fails to account for the fear, anxiety, and distress experienced by the animals during the procedure and demonstrates a serious violation of accepted veterinary protocols and ethical standards set by CCSEA for euthanasia.
11.	Record	No	There is a glaring absence of a proper record-keeping system to ensure the health and welfare of animals in the custody of PBPL.
	a. Permits (breeding, use and reuse)	Yes	PBCL shared the approval orders.
	b. Procurement records	No	PBPL failed to furnish any documentation or records to substantiate otherwise.
	c. Breeding record	No	PBPL failed to furnish any documentation or records to substantiate otherwise.
	d. Health records (for each animal)	No	The available documentation at PBPL consists of loose paper sheets—standard forms filled out seemingly to meet the requirements of the contracting client. These documents capture isolated cases or incidents and are submitted to the record room immediately after data entry.

			Critically, they fail to provide any comprehensive overview of essential information such as the total number of animals used, the frequency of their use in experiments, clinical conditions identified, or the preventive and therapeutic care administered—whether at the breeding facility or the experimentation centre. This fragmented and superficial record-keeping reflects a seriously negligent approach to both regulatory compliance and animal welfare standards. Moreover, veterinary records were not available on-site, significantly hampering the ability to conduct thorough inspections or continuous assessments of animal health and well-being. Without access to these records, it is impossible to monitor medical histories, vaccination status, or previous treatments—elements that are vital to ensuring timely and appropriate veterinary care. The absence of a structured, accessible veterinary documentation system undermines the facility's responsibility to safeguard the animals in its custody.
	e. Sale & transfer records	No	PBPL failed to furnish any documentation or records to substantiate otherwise.
	f. Surveillance records	No	PBPL failed to furnish any documentation or records to substantiate otherwise
	g. Rehabilitation cost records (if any; please state if no cost is undertaken)	No	PBPL failed to furnish any documentation or records to substantiate otherwise. However, this may be verified through the CCSEA, as such reports are mandatorily required to be submitted to them.
12.	Quarantine protocols	No	There is a complete absence of dedicated quarantine facilities across all animal housing units at PBPL, including those for monkeys, dogs, sheep, minipigs,

			and mixed-breed pigs. No separate rooms or designated areas have been established for quarantining new arrivals or isolating potentially sick animals, posing a significant risk to animal health, biosecurity, and disease containment. Primates (*Macaca mulatta*) are sourced from CCSEA-approved vendors and are wild-caught. PBPL informed that the current screening protocol for monkeys does not include Kyasanur Forest Disease (KFD)—a zoonotic infection known to be prevalent among monkeys in India. Considering that the monkeys are wild-caught, and in view of the potential biosecurity implications and associated health risks for researchers and staff, including KFD in the screening process would be a prudent and proactive measure. Across all facilities, it was reported that individual cages within shared housing rooms are being used as makeshift quarantine and isolation spaces. This practice falls far short of accepted quarantine protocols and fails to provide the critical separation needed to prevent cross-contamination. The absence of proper quarantine infrastructure in a facility housing over 1,500 animals reflects a serious disregard for both animal and human health and welfare. This concern is further exacerbated by the lack of on-site veterinary records, making it impossible to verify health screenings, disease surveillance, or any measures taken to address zoonotic risks.
13.	Welfare, care & veterinary access	No	The overall approach to animal welfare and veterinary care at PBPL reflects a deeply troubling lack of commitment to the health and well-being of the animals in its custody. The organisation

			appears to function primarily as a client-facing entity, with minimal regard for fundamental animal welfare principles, including the prevention of unnecessary pain, suffering, and distress. An anxiety, fear, and distress management protocol is not in place. The experiment conducted on two monkeys—involving an incision near the scapula and insertion of a medicinal repository—is a painful and invasive procedure requiring ongoing wound management. Despite this, the treatment protocol includes only the use of analgesics post procedure completion, while the animals are physically restrained by staff using protective gloves, without the administration of sedatives. This represents a serious lapse in addressing the psychological well-being of animals used in experimentation. Similarly, as reported by the facility's veterinarians, dogs euthanised at the conclusion of research studies are not sedated prior to the administration of thiopentone sodium. Taken together, these practices point to a poorly designed veterinary protocol that fails to adequately safeguard animal welfare during both research procedures and routine veterinary interventions. A critical gap lies in the absence of a functional system for recording preventive healthcare and treatment interventions. No accessible, structured on-site veterinary documentation was available, and existing loose case sheets are reportedly stored in a separate building—severely limiting timely medical assessments and ongoing veterinary oversight. This lack of accessible records undermines the ability to monitor animal health, track vaccination and treatment

			histories, or assess compliance with humane care and regulatory norms. The medical inventory maintained by PBPL is grossly inadequate for a facility housing over 1,500 animals across various species. The central store contained only limited quantities of basic medications such as dewormers, multivitamins, and mineral supplements. Critically, there was no stock of essential medications such as sedatives, analgesics, or anaesthetics, raising grave concerns about the facility's ability to manage anxiety, fear, distress, pain, perform safe medical procedures, or carry out ethical clinical care. While the experimentation room includes a clinical veterinarian and an examination table, there were no emergency or pain-management medicines available at the site for immediate intervention. This further reinforces the perception that PBPL's role is largely confined to conducting studies that culminate in euthanasia, necropsy, and histopathological examination, rather than ensuring ongoing health and welfare. Environmental conditions within the facility were also suboptimal. The breeding facility recorded elevated humidity across all areas remained around 86%. Moreover, there was a complete absence of essential infrastructure—no dedicated quarantine areas, no isolation wards for sick animals, and no grooming or exercise facilities. This was consistent across all large animal species, including monkeys, dogs, sheep, minipigs, and pigs, and represents a systemic failure to uphold even the minimum standards of animal welfare. Of the four veterinarians reportedly assigned to 13

			experimental facilities, only two were present at the time of inspection—raising serious concerns about the adequacy of veterinary coverage and timely access to care. In the absence of regular veterinary supervision, dedicated treatment spaces, and structured welfare protocols, animals remain at significant risk of untreated medical issues and unnecessary suffering. In conclusion, the conditions observed at PBPL point to substantial deficiencies in veterinary access, preventive healthcare, and critical welfare infrastructure. These shortcomings compromise both the physical well-being and dignity of the animals and present serious ethical and regulatory concerns that warrant urgent attention.
14.	All experiments conducted/being conducted are approved?	Inconclusive	PBPL failed to furnish any documentation or records to substantiate otherwise.
15.	Segregated housing for rehabilitated vs experimental animals?	Yes	Although the rehabilitation facility is separate from the experimental units, the housing conditions in both are virtually identical—enclosed, temperature-controlled rooms where animals are confined to cages without any form of environmental enrichment. Consequently, the quality of life in the so-called rehabilitation setting is indistinguishable from that of the experimental facility and falls significantly short of the fundamental principles and intended goals of true rehabilitation.
16.	Adequate shelter (space, ventilation, hygiene)?	No	As outlined in the section on housing conditions for animals bred and used in experiments, while the space provided is generally inadequate, the breeding facilities also lacked proper ventilation and were marked by poor hygiene standards. In contrast, the experimental facility

			showed marginal improvements in air-conditioning and cleanliness; however, fundamental welfare concerns persisted across both settings.
17.	Clean water and species-appropriate food available?	No	Water was provided via a drip pipe system. All species were offered packaged dry commercial feed: dogs received 300 grams once daily; minipigs were provided 500 grams per day; and monkeys were fed 150 grams of pellets along with fruits and a bun each day. In the case of dogs—specifically adult Beagles—the fixed ration of 300 grams of dry commercial pellets per day is likely insufficient to meet their daily caloric and nutritional requirements. Moreover, a single daily feeding is not aligned with standard welfare practices for laboratory-housed dogs, particularly Beagles, which benefit from multiple feedings and enrichment. Thus, the current feeding regime may contribute to nutritional imbalance and does not reflect best practices in animal nutrition and welfare management.
18.	Veterinary care accessible at all times?	Inadequate	Veterinary care at PBPL is available only between 9:00 a.m. and 5:30 p.m., with no veterinarian coverage during night hours. Although technicians are reportedly present on campus overnight, they are not stationed on the animal floors. Critically, both the breeding and experimentation centres lack essential veterinary medicines, including those necessary for emergency care, pain relief, or disease prevention. In the absence of these fundamental medical supplies, veterinarians are effectively unable to provide any meaningful treatment or alleviate unnecessary pain and suffering. As a result, there is no 24x7 functional veterinary system in place to safeguard the health and

			welfare of the large number of animals currently housed at PBPL.
19.	Daily monitoring and health logs maintained?	No	The veterinary logs, maintained as loose case sheets, lack essential clinical details—such as observed clinical signs, diagnostic assessments, and medications administered. This incomplete and inconsistent documentation renders the recording system ineffective, offering no tangible benefit to the animals' health, treatment, or ongoing care.
20.	Animals being reused are healthy and with approved?	No	PBPL failed to furnish any documentation or records to substantiate otherwise. A detailed micro-audit is necessary to determine the frequency of reuse of individual animals and to assess whether such practices are in compliance with the specific permissions granted by the CCSEA.
21.	Was CCTV footage made available and accessible during the inspection, and were there any notable findings or issues observed?	No	CCTV footage was not made available to the CCSEA inspection team despite multiple formal and verbal requests on the day of the visit, as well as prior intimation through an official CCSEA letter. The team was later informed that the designated custodian of the CCTV system was unavailable, and therefore, recordings could not be accessed during the inspection—even though senior management was present and expressed helplessness in resolving the issue. Management subsequently assured the team that online access to the CCTV footage would be facilitated the following morning, once the operator was on duty at 9 a.m. During a Microsoft Teams meeting held the next day, the dashboard monitor displaying live CCTV camera feeds was shared with the inspectors. However, despite repeated and specific requests, the team was not shown any recordings from the corridors

			of the dog breeding stock areas. Staff claimed that no cameras were installed in those particular locations, leaving a critical gap in visual documentation. Similarly, when the team requested footage from the rehabilitation area, animal entry, and the dirty corridors of the experimental housing zones, they were again informed that no CCTV cameras had been installed in those areas either. Notably, only one camera was found to be recording the presence of AWBI inspectors near the corridor of the rehabilitation centre—despite the fact that the inspection team was present there from 2:30 p.m. until late at night. The inspection team is of the opinion that this lack of access to key CCTV footage, combined with the absence of camera coverage in critical areas, indicates a deliberate attempt to withhold or tamper with evidence related to potential animal welfare violations. For a facility housing thousands of animals, CCTV should be a primary tool for monitoring and preventing cruelty. In this case, the system appeared to be non-functional—or at least non-operational—for the CCSEA inspectors, raising serious concerns about transparency and accountability at PBPL.

V. Non-Compliances Related to the Prevention of Unnecessary Pain and Suffering in Animals

Contrary to the mandates set forth by CCSEA regulations and guidelines, a case study based on data from the software application used at PBPL's experimentation facility revealed serious lapses in animal welfare. In one instance, a dog exhibiting mild to moderate tremors was not withdrawn from the experiment. The symptoms reportedly progressed to severity and became severe by the tenth day. The animal was then marked as "removed" and "killed-moribund" on the twelfth day.

The terminology used in the software—"removal" and "killing-moribund"—is ambiguous and fails to clarify whether any action was taken to alleviate the animal's suffering during this period. As per regulatory guidelines, an animal exhibiting significant neurological symptoms

such as tremors, indicative of high drug toxicity, should be promptly removed from the study and provided with appropriate medical intervention. In this case, both the researcher and the clinical veterinarian failed to take timely action.

Moreover, the software did not provide any detailed account of the animal's clinical parameters, additional symptoms, or medications administered. Although the clinical veterinarian claimed that such records were maintained on loose sheets using a fixed format, she was unable to produce the relevant documentation even after an extensive search. This raises serious concerns about the absence of evidence-based health monitoring or treatment interventions at PBPL.

The lack of a minimum stock inventory of drugs, instruments, and surgical supplies at the examination areas of each experimentation room further compounds the situation, underscoring the extent of cruelty to animals, compromise of animal welfare, and potential regulatory violations at the facility.

There is no protocol to address anxiety, fear, and distress in animals at the facility. In a recent invasive experiment on two monkeys involving surgical implantation and daily wound care, only analgesics were used post procedure, with physical restraint applied without sedatives—indicating serious neglect of psychological welfare. Similarly, dogs euthanised at the end of research studies were not sedated prior to the administration of thiopentone sodium. These practices highlight critical flaws in the veterinary protocol, failing to meet even the basic standards for preventing unnecessary pain and suffering.

Moreover, the use of nomenclature such as "removal" and "killed" in official records reflects a troubling level of insensitivity by the establishment and its personnel toward animals as sentient beings. This choice of language stands in stark contrast to the terminology mandated by CCSEA regulations, which explicitly call for the use of the term "euthanasia"—denoting a "good death" that is humane, compassionate, and ethically conducted. The terminology employed at PBPL not only lacks clarity but also suggests a disregard for the ethical principles embedded in the regulatory framework.

VI. Euthanasia

It was reported that euthanasia is a routine and significant procedure at PBPL, primarily overseen by the pathology department. According to both records and the veterinarian in charge, approximately 30–40 dogs are euthanized each month. These procedures are followed by gross pathological and histopathological examinations, the findings of which are appended to the respective research data.

However, several deeply concerning observations emerged during the inspection. The attending veterinarian confirmed that no sedatives are administered prior to euthanasia to mitigate fear, anxiety, or distress. Instead, thiopentone is injected slowly while an assistant physically restrains the animal—an approach the veterinarian himself acknowledged he would not use if the procedure were a routine surgery such as spaying or castration, or if the breed were less docile, such as a Bulldog, Dobermann, or Rottweiler. This underscores a troubling reliance on the naturally gentle and submissive temperament of Beagle dogs, which makes them easier to handle and restrain, even under distressing conditions, without adequate measures to reduce suffering.

Alarmingly, despite the high frequency of euthanasia, only 20 vials of thiopentone were available at the pathology department, with no stock visible in the central store. This raises serious concerns about whether euthanasia procedures are being conducted consistently with proper dosing and humane practices.

The sheer number of euthanasia cases also suggests that a significant proportion of the animal population is being killed as part of experimental protocols. This may further explain why only 73 dogs were found in the rehabilitation section—a number that appears disproportionately low relative to the reported usage and turnover.

VII. NGO Involvement in Rehabilitation:

Dogs are currently rehabilitated within PBPL's own facility. No records were made available to the inspection team indicating that animals had been transferred to AWBI-recognised animal welfare organisations. Additionally, there was no documentation provided regarding any Memoranda of Understanding (MoUs) or financial support extended to such organisations for the long-term care of the animals.

VIII. Lack of Transparency in Animal Use and Research Practices

During the inspection, the presence of mixed-breed pigs and sheep was repeatedly denied by the facility staff, despite direct and repeated queries from the inspection team. This immediate lack of disclosure raised serious concerns about transparency and the intent to obscure critical information.

Further compounding these concerns, the presence of mixed-breed pigs was inadvertently confirmed when a researcher referenced their use in cardiological studies, including pacemaker development. This was followed by the inspection team observing a separate room housing sheep—despite earlier denials. When committee members proceeded to assess these areas, staff at both the breeding and experimental facilities refused to switch on the lights. They cited adherence to Standard Operating Procedures (SOPs) governing lighting schedules. However, this explanation was inadequate in the context of a formal regulatory inspection and effectively obstructed visibility, thereby preventing a thorough evaluation of the animals' housing conditions.

In addition, a clear inconsistency was observed between the number of CCSEA-approved research protocols—reported to be 87 over the past three months—and the actual number of dogs, minipigs and monkeys present at the facility. This discrepancy suggests possible non-compliance with approved study limits or underreporting of animal populations.

Crucially, the mandatory three-month washout period—required to ensure complete elimination of substances from animals' systems before reuse—was reportedly not being followed, particularly for minipigs. No documentary evidence was produced during the inspection to verify compliance with this requirement. This lapse not only violates standard ethical and scientific guidelines but also compromises the validity of subsequent research and the welfare of the animals involved.

Overall, the number of animals observed during the inspection did not align with the facility's declared housing capacity or the volume of CCSEA-approved experimental protocols. The presence of surplus, unscreened stock animals in experimentation rooms points to serious gaps in documentation and oversight. These findings underscore the urgent need for a detailed review and reconciliation of animal usage records to ensure compliance with regulatory requirements and to uphold fundamental animal welfare standards.

IX. CCSEA Inspection Team's Observations in Relation to Specific Allegations Raised by PETA-India's Alleged Whistle-blower

Animal Species	Complaint Category	Specific Allegations by PETA	CCSEA Inspection Team's Observation
Confirmation of Location of Reported Incidents	**General**	Allegations of cruelty to animals and violations of animal protection laws occurring on the premises of PBPL.	The visuals presented in PETA-India's investigation video were found to match the premises of PBPL. The PBPL management acknowledged that certain footage—such as holding a dog by the scruff—was taken from a training video and claimed it is not representative of routine practice. However, they disputed some visuals, asserting that these either originated from another facility or had been manipulated.
Beagles (Dogs)	**Overcrowding & Housing**	Approximately 1,500 dogs housed in a space designed for 800, forcing 3-4 dogs into cages meant for two. Breeding facility reportedly concealed from various auditors.	At the time of inspection, 2-3 dogs per kennel were noted in each of the breeding stock modules; the whelping mothers were housed with their puppies. An overall high housing density of dogs was observed in the breeding modules, and excess breeding stocks were found to be housed in dog experimental areas. The facility's manager was unable to determine the accurate number of total dogs present, indicating potential overcrowding possibilities. Furthermore, CCTV footage from the corridors of the dog breeding stock areas was not made available, with staff asserting that no cameras were installed in those specific areas, which

			could impede verification of housing conditions.
	Breeding Practices	Dogs bred twice a year, often exceeding the company's stated policy of a maximum of five breeding cycles. Dogs as old as 13 years allegedly used for breeding, causing immense physical strain and increasing risk of difficult labor.	Consolidated breeding records and veterinary care of dogs were not available on-site within the dog breeding area. The overall high housing density of dogs in the breeding modules and the facility manager's inability to determine the correct number of dogs present suggest practices that could lead to overbreeding and exceed capacity.
	Lack of Care & Handling	Overcrowding led to frustration, food aggression, and frequent fights, causing serious injuries (especially to ears). Company allegedly failed to provide basic care, including proper wound cleaning and pain management. Workers observed handling dogs roughly, kicking them, and carelessly closing cage doors on their legs. Dogs picked up by the scruff of the neck or skin on their backs.	At the time of inspection, no seriously injured animals were observed. However, the inspection team noted an overall high housing density of dogs in breeding modules, accompanied by extreme decibel levels of barking. A few dog kennels in the breeding stock area were observed to house animals in poor body condition, some showing signs of cherry eye, with dirty conditions and an overall uninviting environment. The veterinary records for the animals were not present on-site, which significantly hindered inspectors ability to monitor medical history or verify proper wound care and pain management. No CCTV is installed at an angle that would allow visualization or recording of individual dogs.
	Medical Neglect & Suffering	Dogs developed abscesses, ulcers, and signs of severe pain following subcutaneous injections of	The complete absence of on-site veterinary records for the animals precluded the inspection team from

		test compounds. Injection sites became inflamed or developed open wounds, with infections potentially spreading. In some studies, dogs became very ill, with one reportedly vomiting excessive quantities of blood before dying. Some suffered ulcers in mouth and intestine from oral dosing.	verifying specific claims of abscesses, ulcers, severe pain, or other medical conditions and their treatment. However, the team observed a few dirty kennels and very high relative humidity levels (80-97%) in nearly all rooms, which can create an environment conducive to health problems and infections. Furthermore, the recording of adverse reactions in study-based software were poorly recorded or, apparently, not recorded.
	Euthanasia Protocol Violations	"Humane endpoints" existed only on paper; management instructed veterinarians to delay euthanasia for suffering animals until sponsor permission was granted. Dogs allegedly killed using thiopentone without prior sedation.	The euthanasia is performed by the veterinary pathologist using approved drugs. However, in the case of dogs, sedation or tranquilization prior to euthanasia is not practiced.
Minipigs	**Unlicensed Breeding & Euthanasia**	Company purchased Göttingen minipigs but lacked a license to breed them. Accidental pregnancy led to euthanasia of 8-10 piglets via intracardiac injection without prior sedation.	Minipigs were present at the facility. A noticeable inconsistency was observed between the number of CCSEA-approved research protocols and the actual population of minipigs housed, which raises questions regarding breeding. The absence of on-site veterinary records further prevented verification of euthanasia for piglets, if any.
	Lack of Enrichment	Despite a written policy requiring playtime and social enrichment for pigs, the Company routinely failed to provide either. Enrichment only provided when external visitors were present.	A notable deficiency in environmental enrichment was observed for minipigs, with only a few provided with cut sections of PVC pipes, which failed to engage them and left them visibly uninspired and bored.

			Provision for playtime outside cages is not available.
	Improper Housing	Representatives from the Danish supplier observed pigs' feet getting injured due to improper flooring.	All animals, including minipigs, were confined exclusively in cages with fibber-reinforced polymer flooring. However, the absence of on-site veterinary records for the animals precluded the inspection team from verifying specific claims of pigs' feet getting injured and their treatment.
Monkeys (Rhesus Macaques)	**Illegal Capture & Transport**	Company allegedly captured 14 rhesus macaques from the forest in Rajasthan, exceeding government permission for 12. Monkeys (approx. 1.5 years old) were sedated and placed in plastic bags, up to five per bag, for transport.	Monkeys were present at the facility and were procured from a CCSEA-registered vendor.
	Zoonotic Disease Risk & Concealment	Two monkeys tested positive for monkeypox in Rajasthan. All monkeys transported together to Telangana facility. The two positive monkeys were killed upon arrival, but others were kept alive despite transport with infected animals. Subsequent re-testing occurred only one week after arrival, despite potentially longer incubation period, as company needed monkeys for client-sponsored test. Company allegedly kept the monkeypox matter quiet, killing infected monkeys without broader disclosure, despite public health risks.	There was a total absence of dedicated quarantine rooms and isolation rooms for sick animals, which critically compromises biosecurity and disease management. The absence of on-site veterinary records further prevented verification of health screenings, disease status, or any actions taken regarding zoonotic diseases.

X. Discussion

The comprehensive inspection of PBPL highlights systemic failures at multiple levels of its operations to uphold animal ethics and welfare as per CCSEA guidelines. PBPL's approach to animal research demonstrates an operational model that prioritizes experimental output over welfare, compliance, and ethical responsibility. Despite its extensive use of dogs, non-human primates, pigs, and other species, PBPL has failed to implement even the most basic standards of care mandated by CCSEA.

Housing conditions were consistently found to be overcrowded, barren, and inadequate, leading to significant welfare concerns such as elevated stress, noise, poor body condition, and heightened risk of infectious diseases. Essential aspects such as environmental enrichment, social interaction, and proper bedding were either entirely absent or grossly insufficient across all species. The breeding facilities were particularly concerning, with overproduction of animals resulting in unauthorized repurposing of experimental spaces as stock rooms, unscreened animal transfers, and potential biosecurity risks.

Veterinary care infrastructure was deeply inadequate. The facility maintained minimal medical supplies, lacked essential analgesics, sedatives, and anaesthetics, and failed to maintain proper treatment records. Notably, no protocol was in place to manage anxiety, fear, or distress—an essential component of humane animal care. Painful and invasive procedures, such as those performed on monkeys involving surgical implantation, were conducted using only analgesics post procedure, with animals physically restrained without sedatives. Similarly, dogs euthanised at the conclusion of research were not sedated before the administration of thiopentone sodium. These practices reflect glaring omissions in veterinary planning and a disregard for psychological well-being.

The animal record-keeping system at PBPL is virtually non-functional, with key regulatory documentation either missing or grossly insufficient. Without breeding records, reuse data, health histories, or procedural logs, PBPL operates in opaque conditions that obstruct regulatory oversight. The deliberate non-cooperation during inspection — notably the failure to provide CCTV footage from critical areas — raises serious questions about transparency and intent.

The inspection also uncovered troubling deviations from approved euthanasia protocols. Animals were euthanised without sedation, relying solely on physical restraint—a practice incompatible with ethical norms of humane care. The high euthanasia rate suggests an unsustainable use pattern where large numbers of animals are systematically killed after experimental use, with limited rehabilitation or rehoming efforts.

XI. Conclusion

The operational deficiencies observed at PBPL are not isolated incidents but indicative of entrenched structural, procedural, and ethical failures. The scale and severity of non-compliances documented during the inspection raise significant concerns regarding the facility's adherence to established standards of animal welfare and regulatory accountability.

The situation demands urgent attention—particularly with respect to the removal and rehabilitation of animals to prevent further pain, distress, or suffering. The findings also call for a critical review of the facility's registration and breeding licence. in view of the serious and repeated deviations from prescribed norms. A detailed micro-audit of PBPL's Institutional Animal Ethics Committee (IAEC) is imperative, including a comprehensive reconciliation of records relating to breeding, procurement, experimentation, reuse, rehabilitation, transfer, euthanasia, and disposal. Such scrutiny is essential to evaluate compliance with approved protocols and to verify the accuracy and integrity of reported data.

XII. Photographic Evidences

Health Condition:

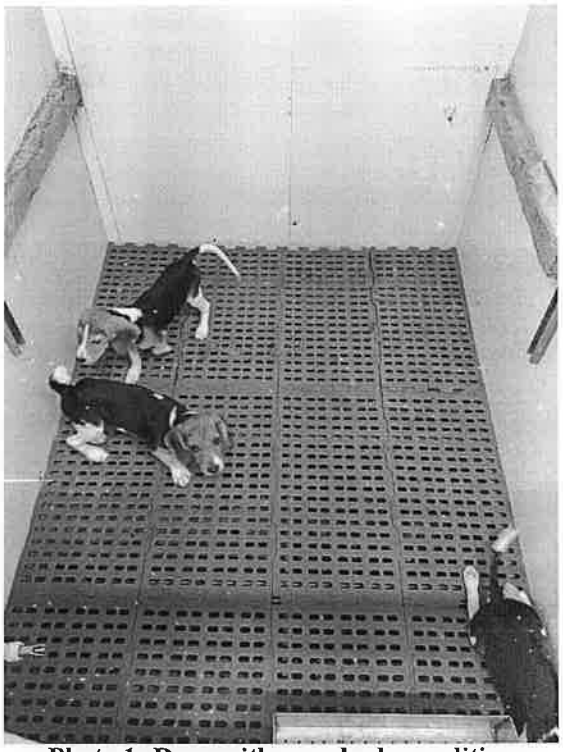


Photo 1: Dogs with poor body condition

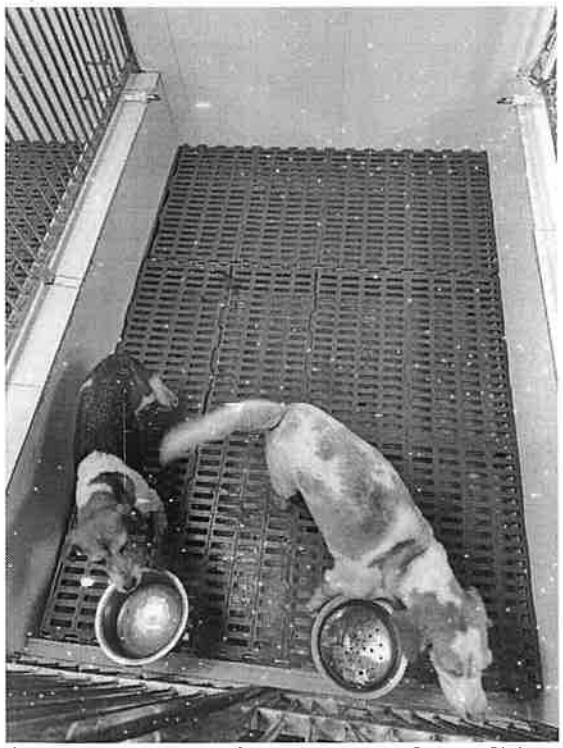


Photo 2: Dog on left with poor body condition

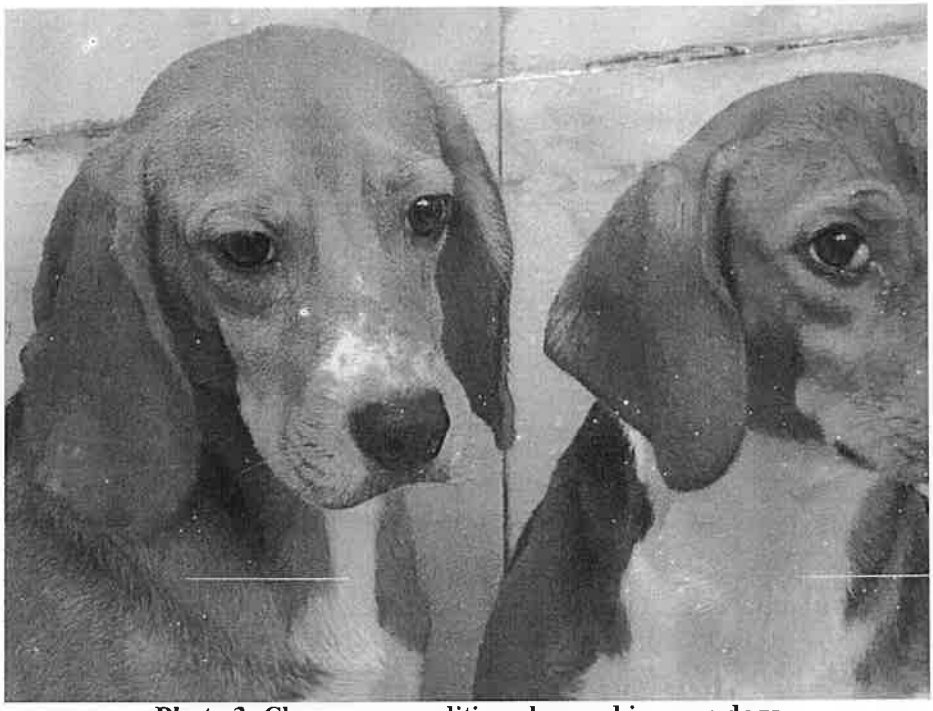


Photo 3: Cherry eye condition observed in some dogs

Photo 4: Cherry eye condition observed in some dogs

Housing Conditions:

Photo 5: No bedding and no enrichment

Photo 6: No bedding and no enrichment

Photo 7: Floor soiled with faeces and in an unclean condition

Photo 8: Floor soiled with faeces and in an unclean condition

Photo 9: Stained and poorly maintained flooring

Photo 10: Stained and poorly maintained flooring

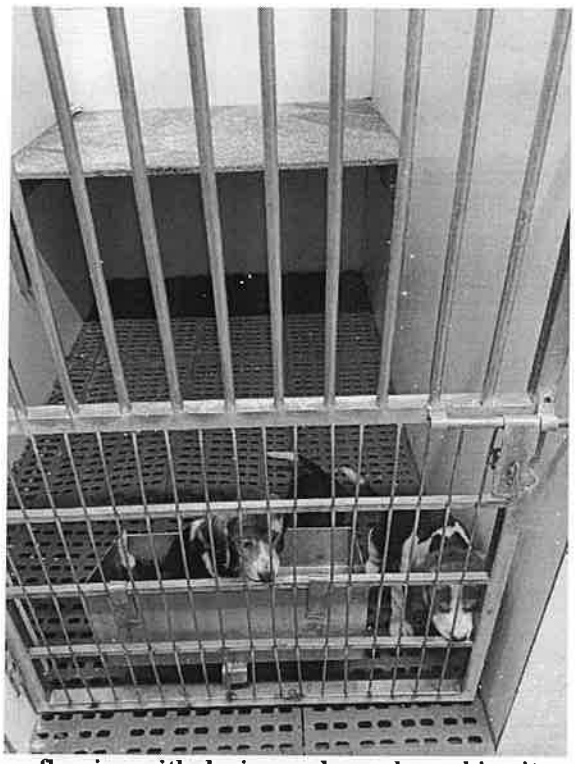


Photo 11: Polymer flooring with drainage channels, making it uncomfortable for animals to stand or lie down

Photo 12: Polymer flooring with drainage channels, making it uncomfortable for animals to stand or lie down

Photo 13: Poorly enriched living conditions with a slippery floor

Photo 14: Poorly enriched living conditions with a slippery floor

Photo 15: Polymer flooring with drains, uncomfortable for animals to stand or lie down

Photo 16: Polymer flooring with drains, uncomfortable for animals to stand or lie down

Photo 17: Enclosed space lacking natural light and enrichment

Photo 18: Enclosed space lacking natural light and enrichment

Photo 19: Restricted movement and lack of socialisation causing significant distress

Photo 20: Poorly designed enrichment tools with limited or no utility

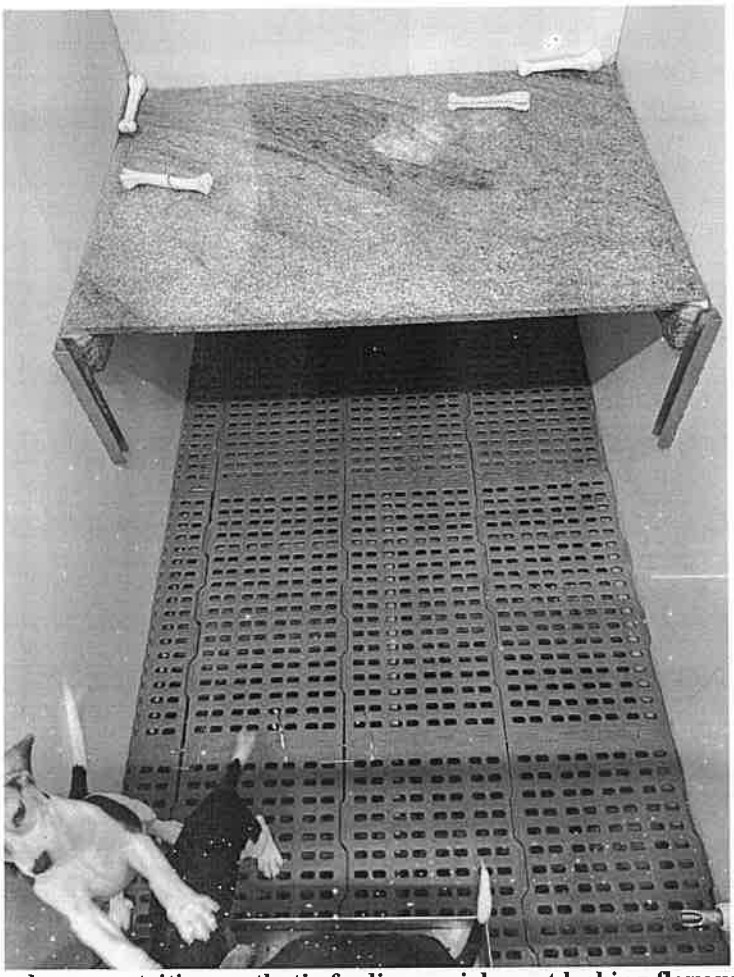


Photo 21: Bland, non-nutritive synthetic feeding enrichment lacking flavour and value

Photo 22: Bland, non-nutritive synthetic feeding enrichment lacking flavour and value

Photo 23: Enclosed space lacking natural light and enrichment

Photo 24: Enclosed space lacking natural light and enrichment

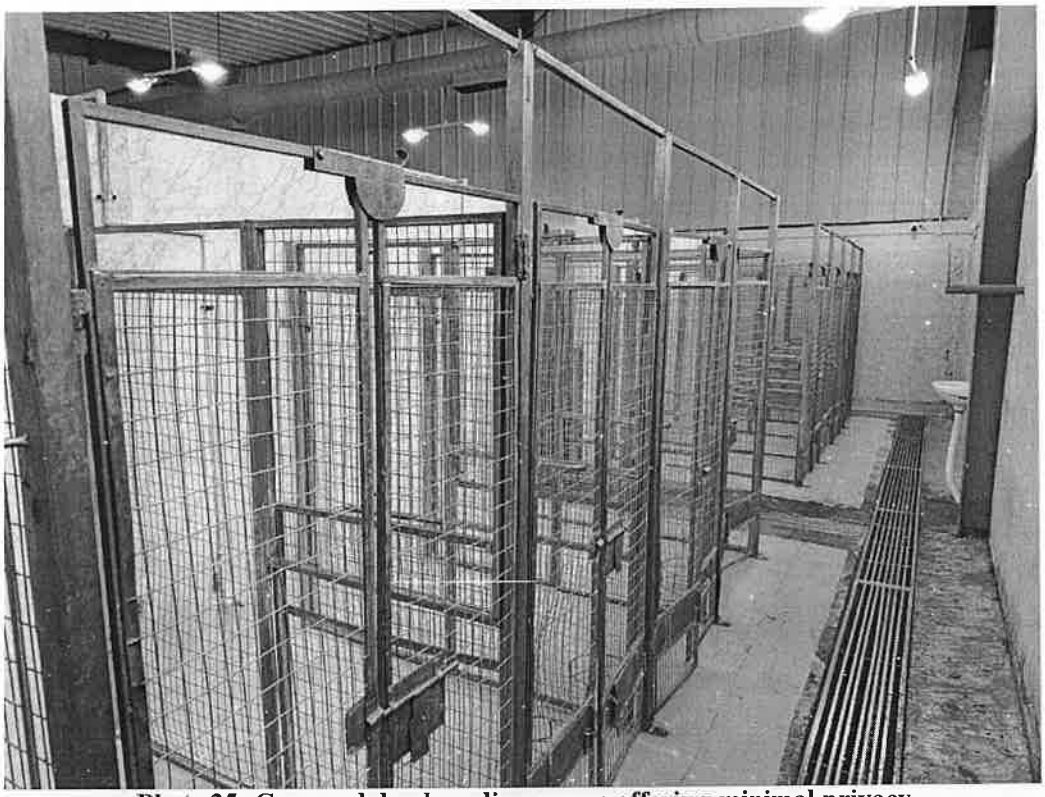


Photo 25: Cramped dog breeding rooms offering minimal privacy

Photo 26: Kennels designed for human cleaning convenience, with flooring and drainage prioritised accordingly

Photo 27: Minipigs housed on uncomfortable flooring with no enrichment

Photo 28: Minipigs housed on uncomfortable flooring with poorly designed enrichment

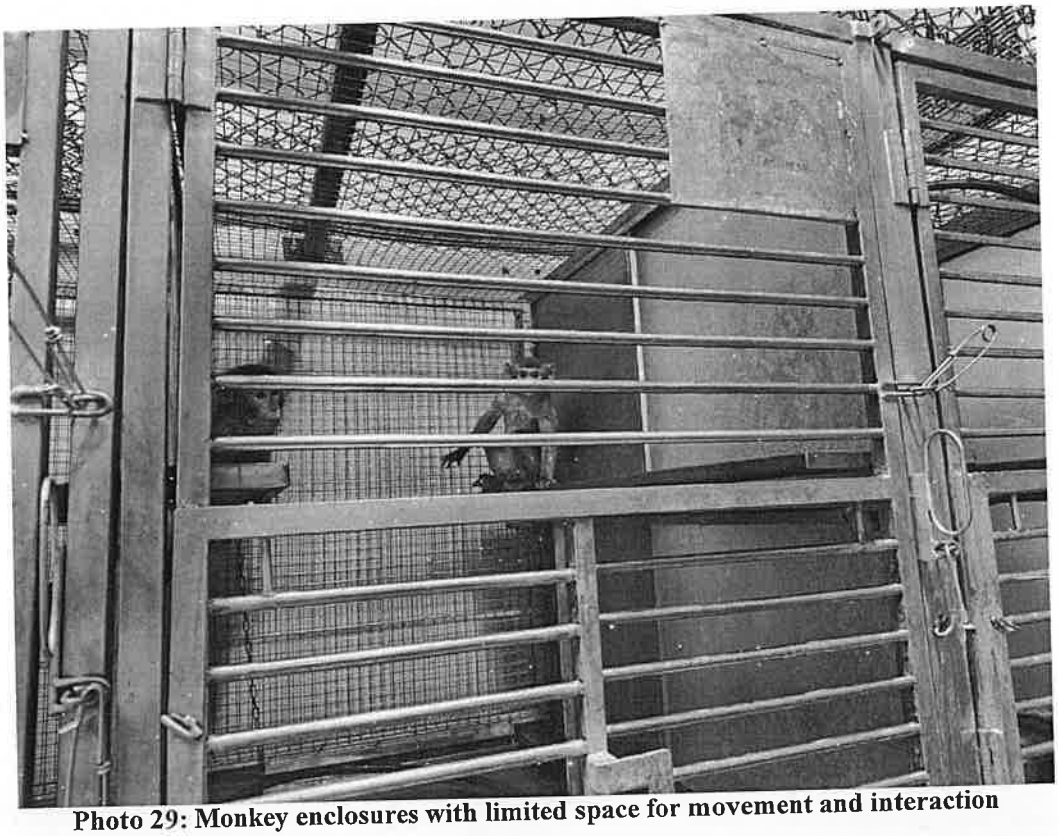


Photo 29: Monkey enclosures with limited space for movement and interaction

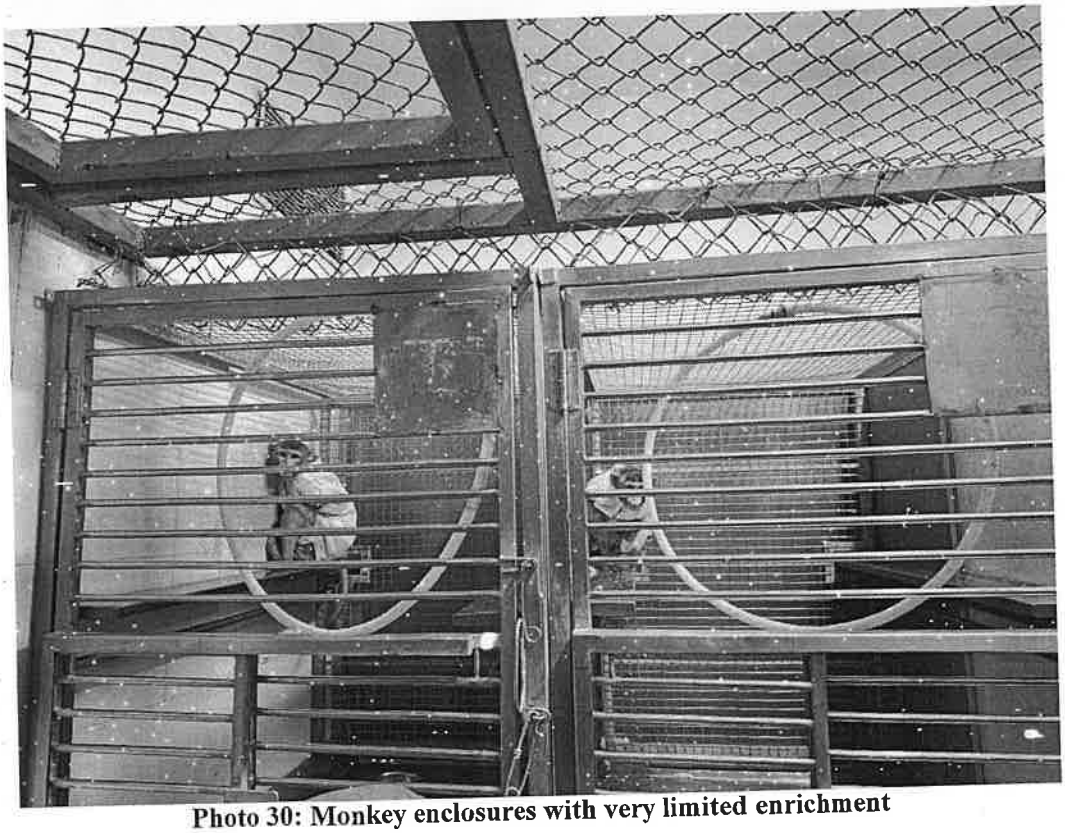


Photo 30: Monkey enclosures with very limited enrichment

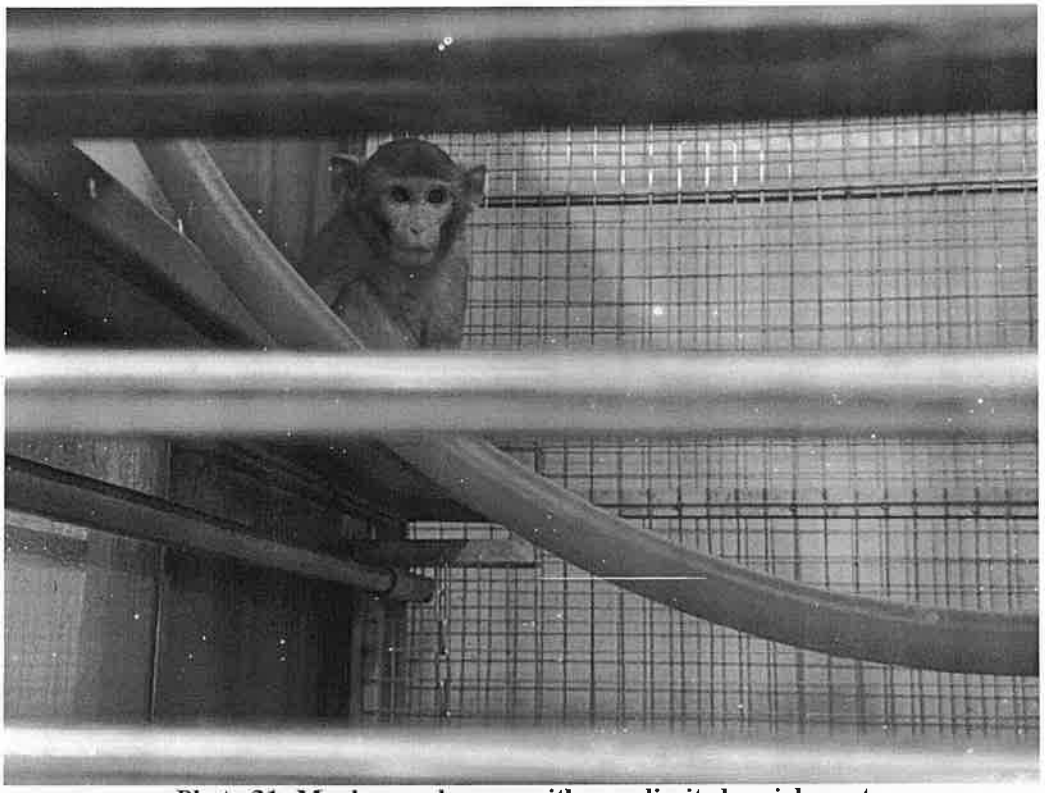


Photo 31: Monkey enclosures with very limited enrichment

Photo 32: Narrow metal platforms restricting animals' comfort while resting

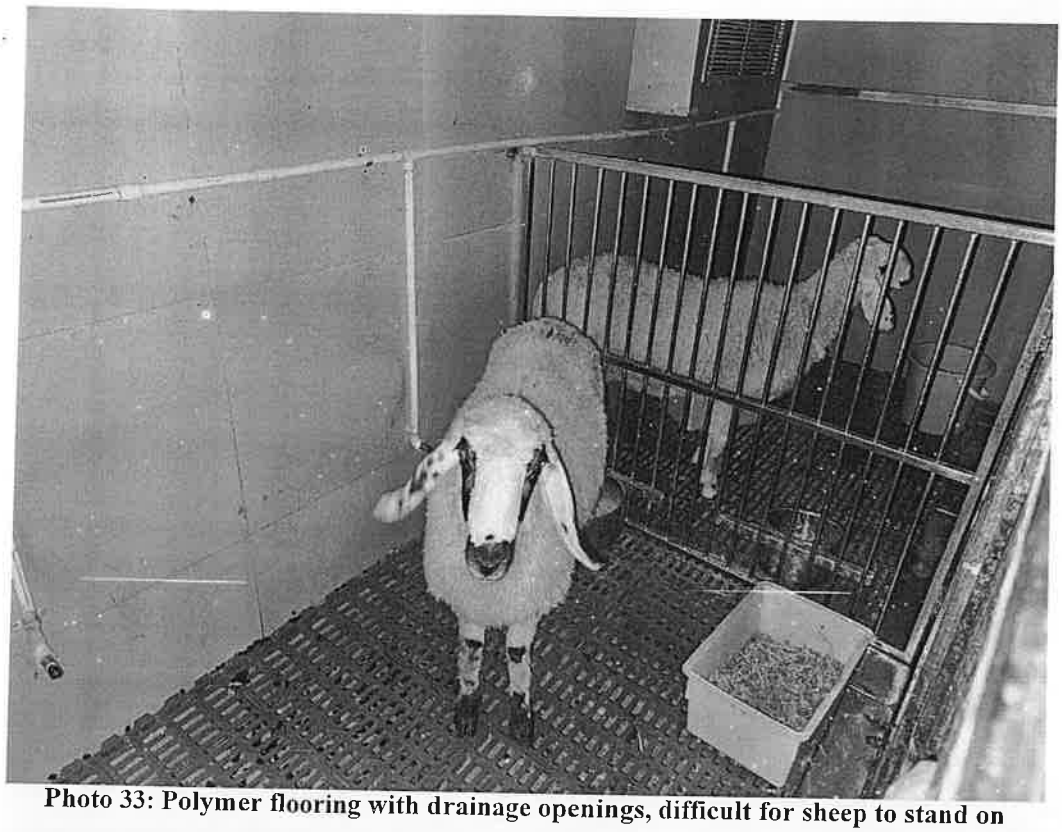


Photo 33: Polymer flooring with drainage openings, difficult for sheep to stand on

Photo 34: Restricted space and lack of socialisation opportunities

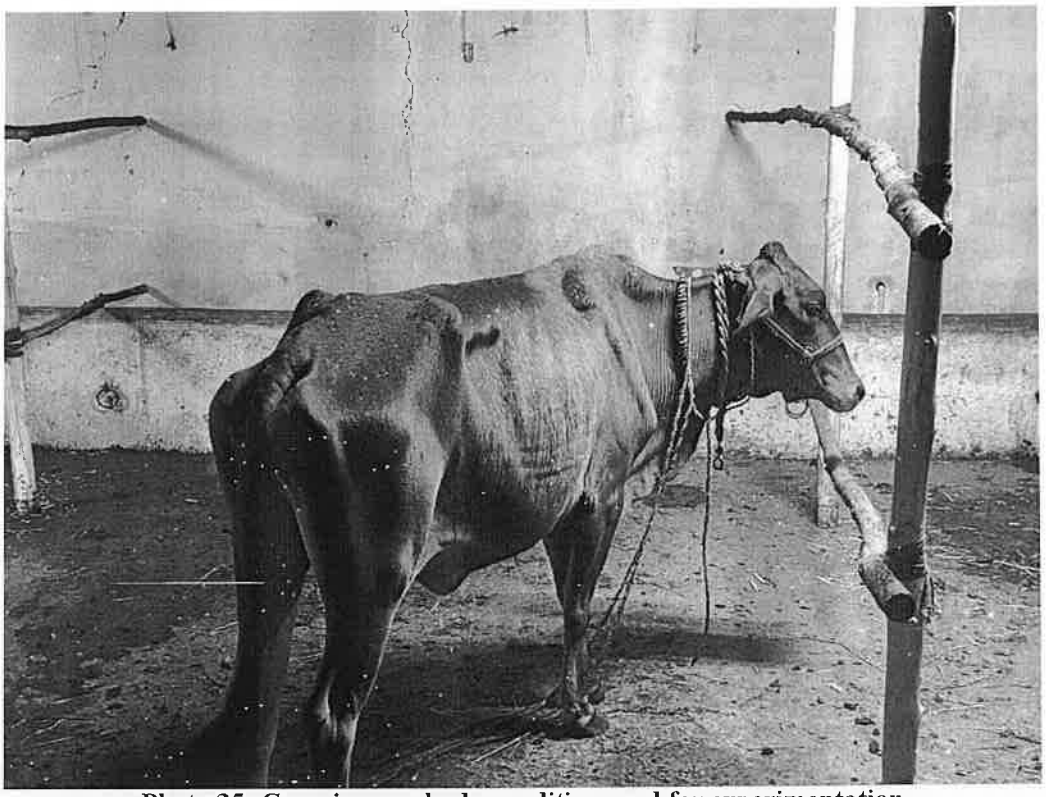


Photo 35: Cows in poor body condition used for experimentation

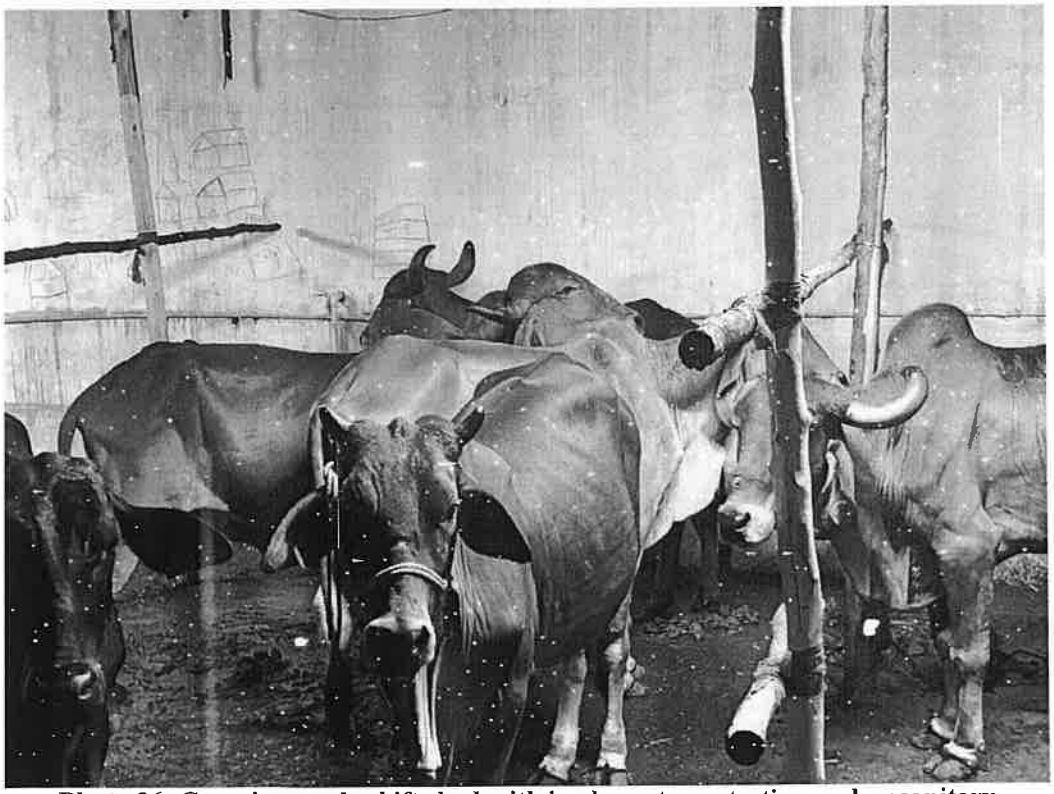


Photo 36: Cows in a makeshift shed with inadequate protection and unsanitary conditions

Medical Inventory:

Photo 37: Medical inventory lacks essentials medicines like sedatives and analgesics

Photo 38: Inadequate medical inventory with only general medicines

Photo 39: Inadequate medical inventory with only general medicines

Photo 40: Inadequate surgical inventory with only general items

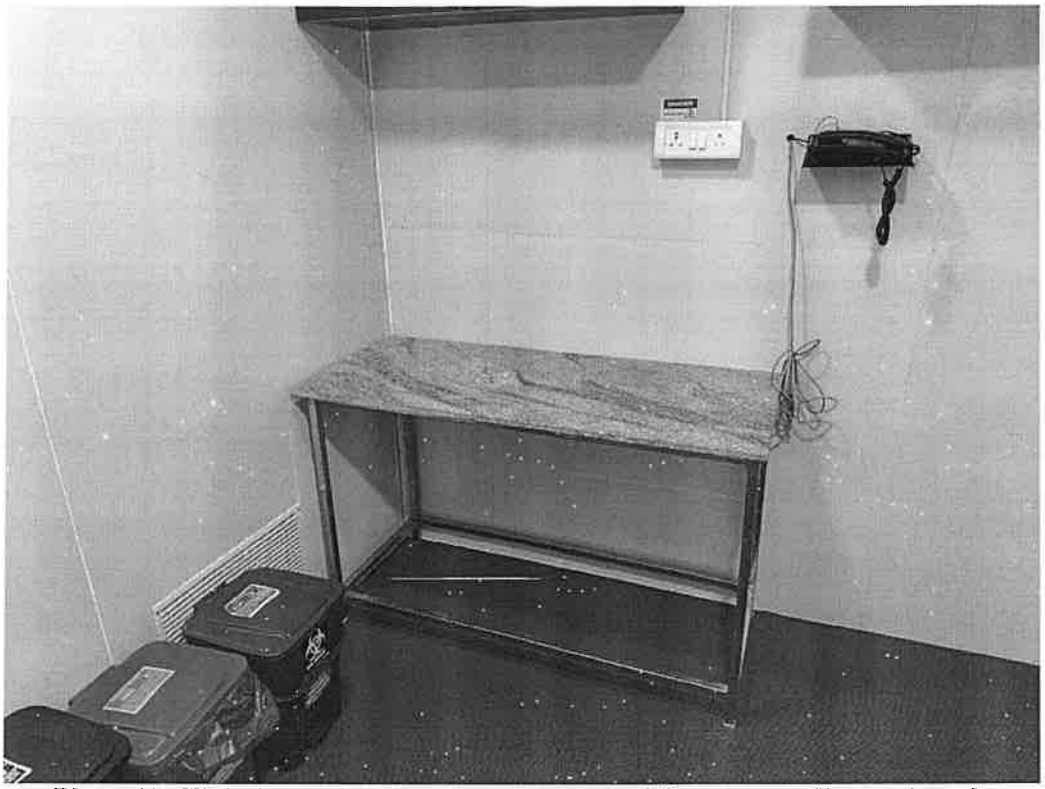


Photo 41: Clinical examination room without medicine stock or diagnostic tools

Photo 42: Clinical examination room without medicine stock or diagnostic tools

Veterinary Documentation:

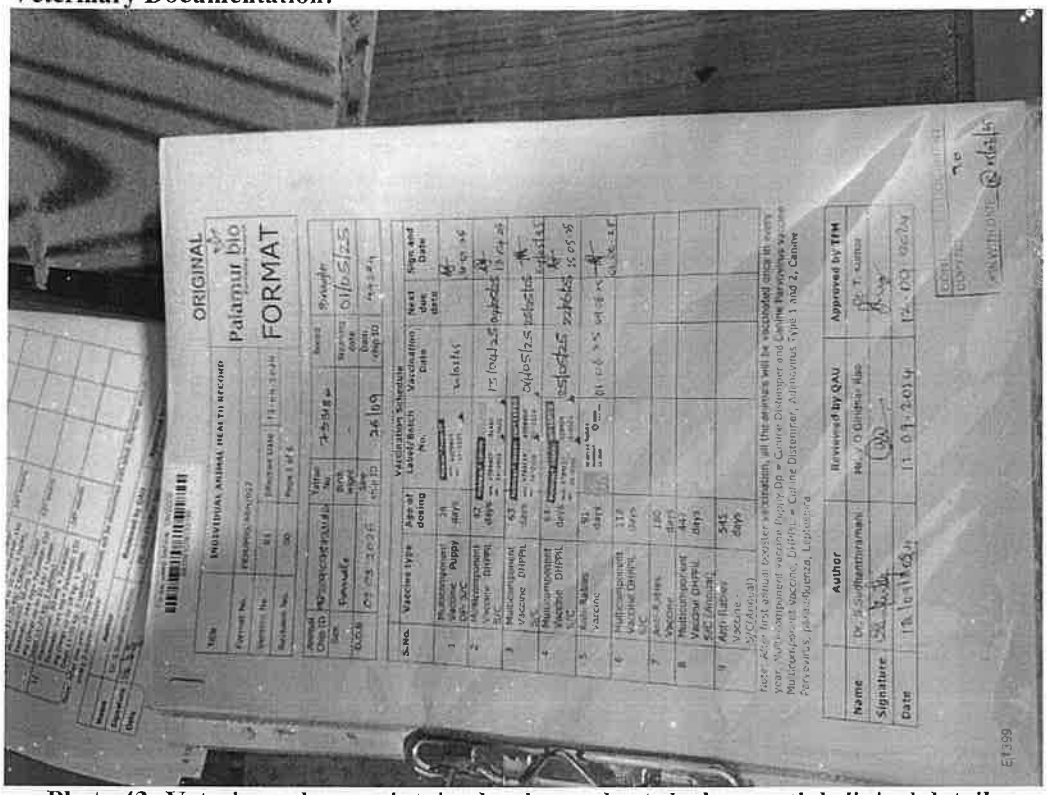


Photo 43: Veterinary logs maintained as loose sheets lack essential clinical details

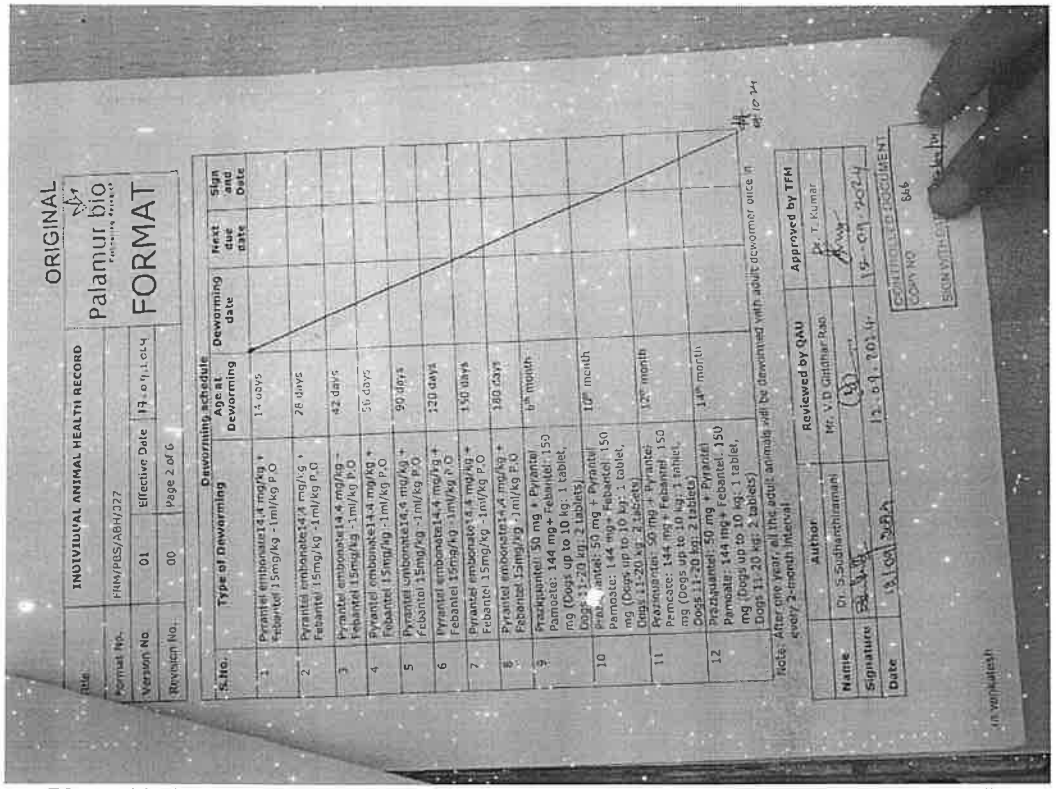


Photo 44: Veterinary logs maintained as loose sheets lack essential clinical details

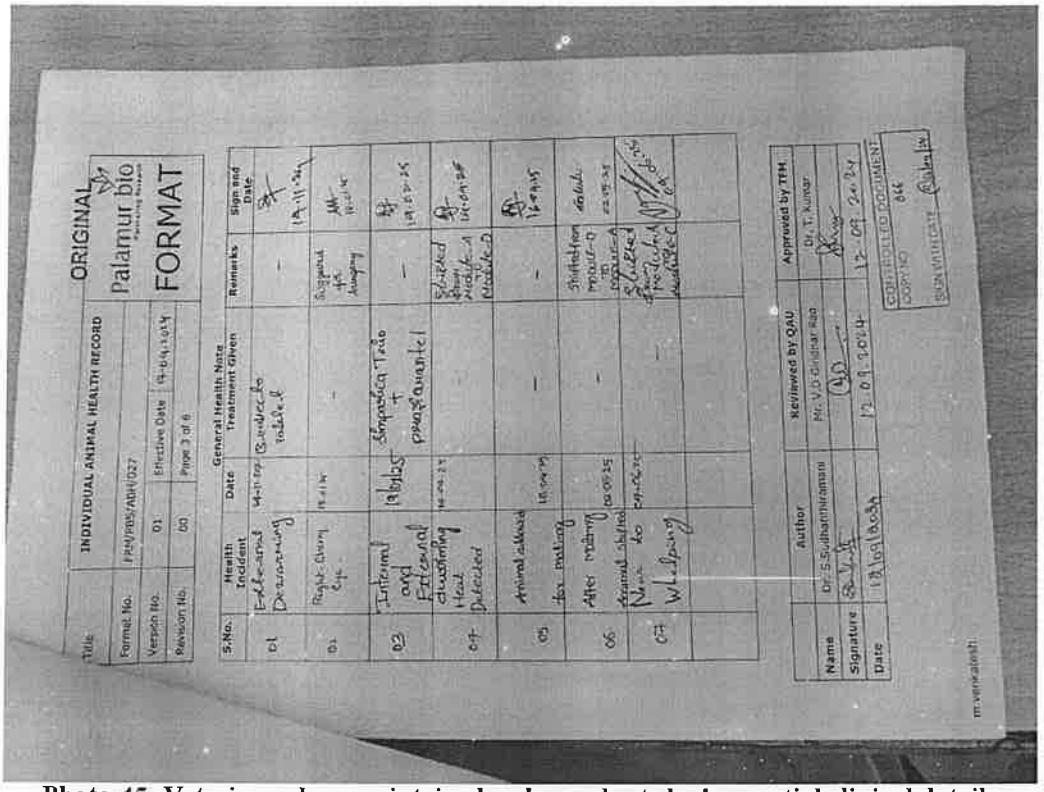


Photo 45: Veterinary logs maintained as loose sheets lack essential clinical details

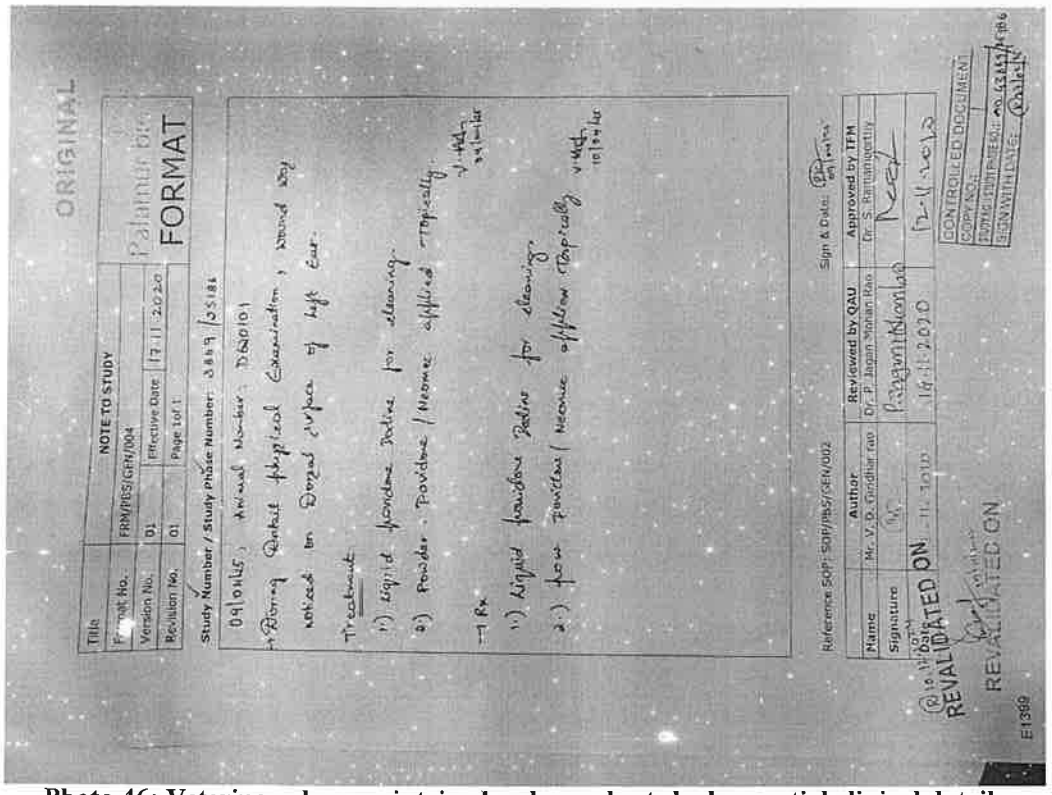


Photo 46: Veterinary logs maintained as loose sheets lack essential clinical details

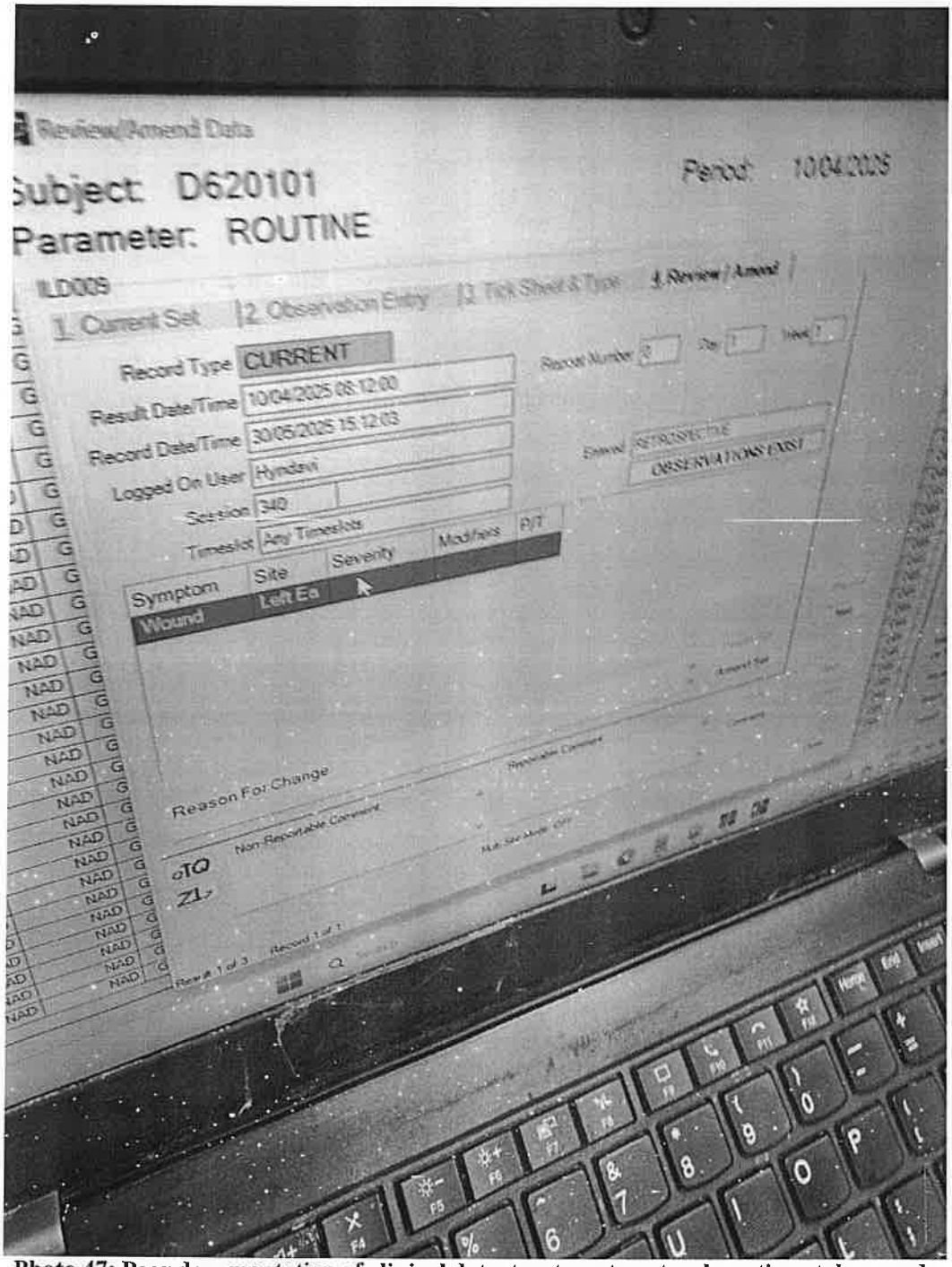


Photo 47: Poor documentation of clinical data, treatment protocols, actions taken, and outcomes

Rehabilitation:

Photo 48: Rehabilitation appears to be a makeshift arrangement, indicated by a paper label affixed to the door

Photo 49: Room and cage design indicate conversion from an experimentation room

Photo 50: Rehabilitation cages lack any form of enrichment

Photo 51: 73 dogs—62 males and 11 females—reported to be under rehabilitation

Euthanasia:

Photo 52: Only 20+ thiopentone vials stocked for 30–40 monthly euthanasia cases

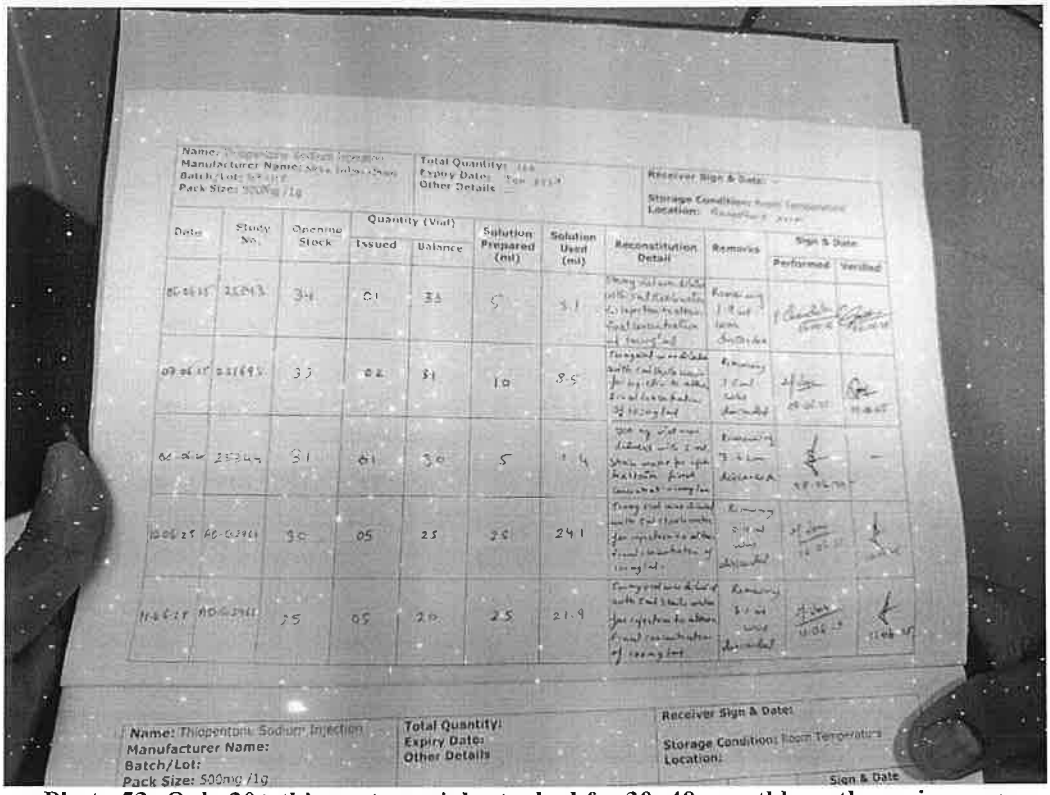


Photo 53: Only 20+ thiopentone vials stocked for 30–40 monthly euthanasia cases

Socialisation Area:

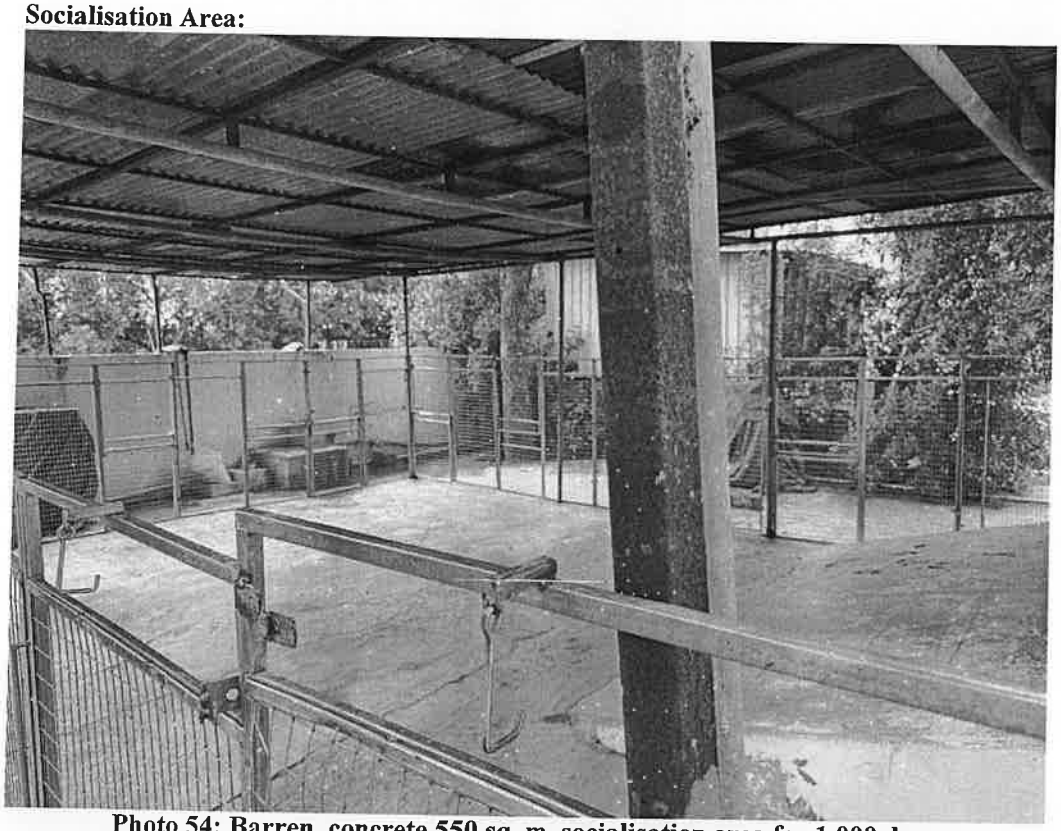


Photo 54: Barren, concrete 550 sq. m. socialisation area for 1,000 dogs

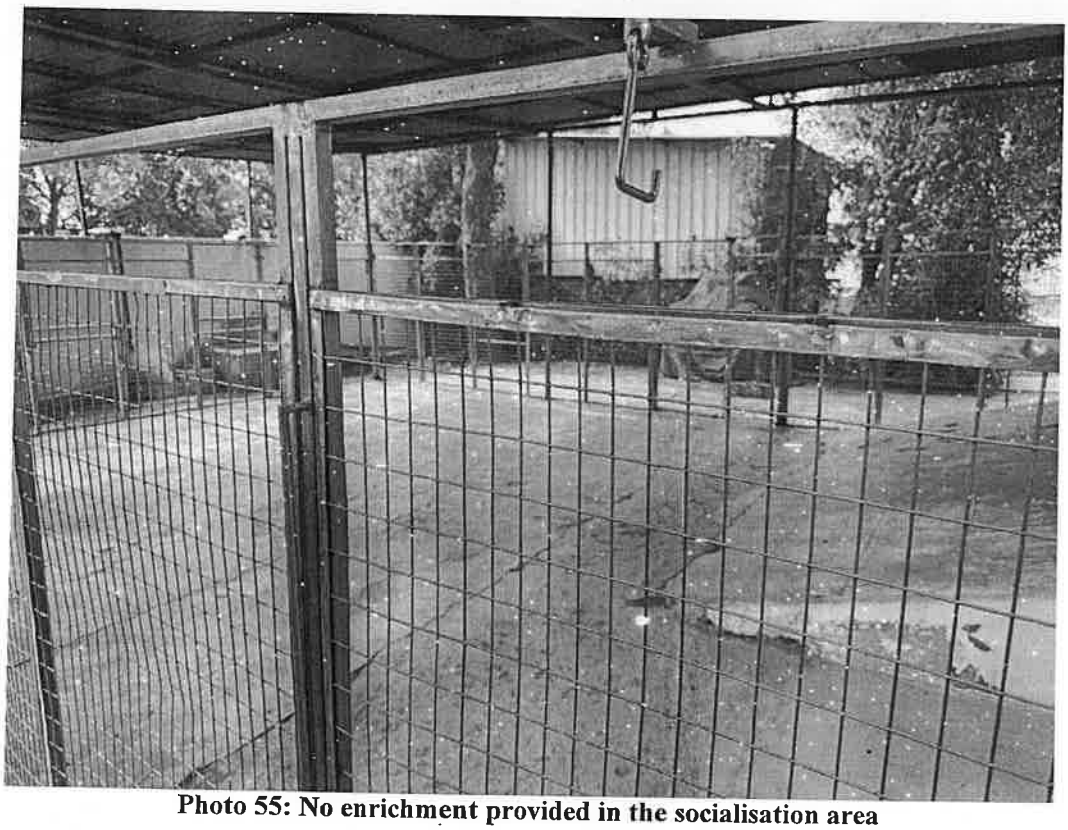


Photo 55: No enrichment provided in the socialisation area

Nutrition:

Photo 56: Animals fed commercial food with limited quantity and frequency

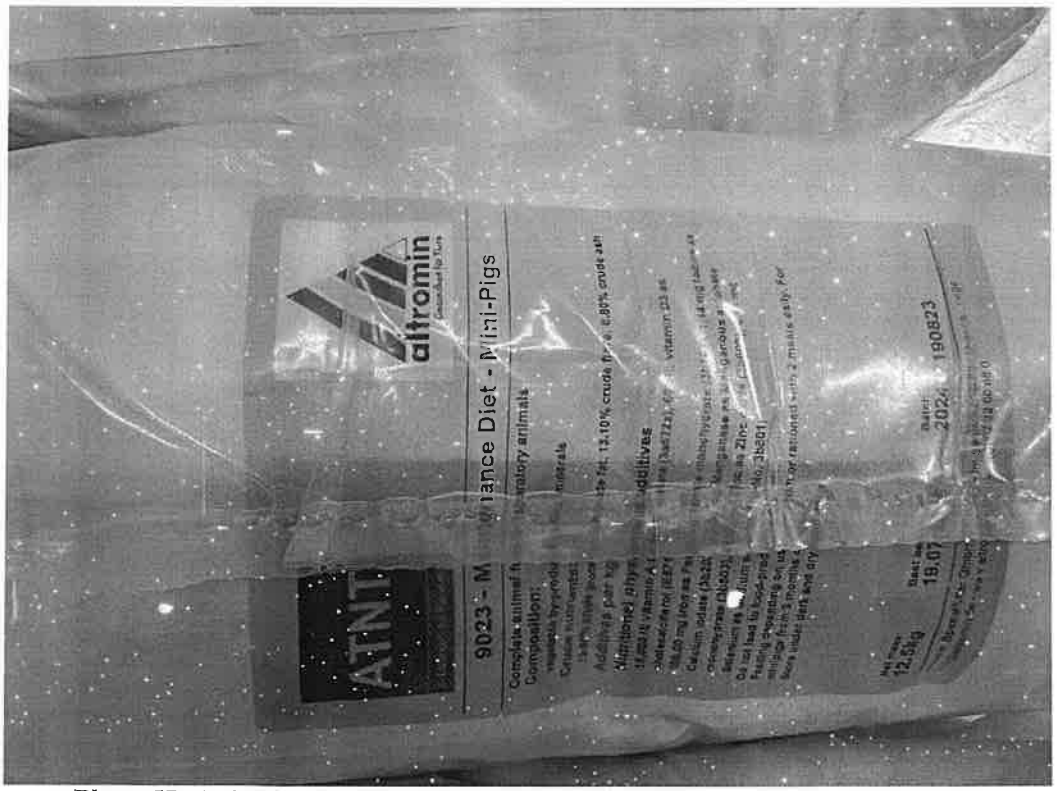


Photo 57: Animals fed commercial food with limited quantity and frequency

CCTV

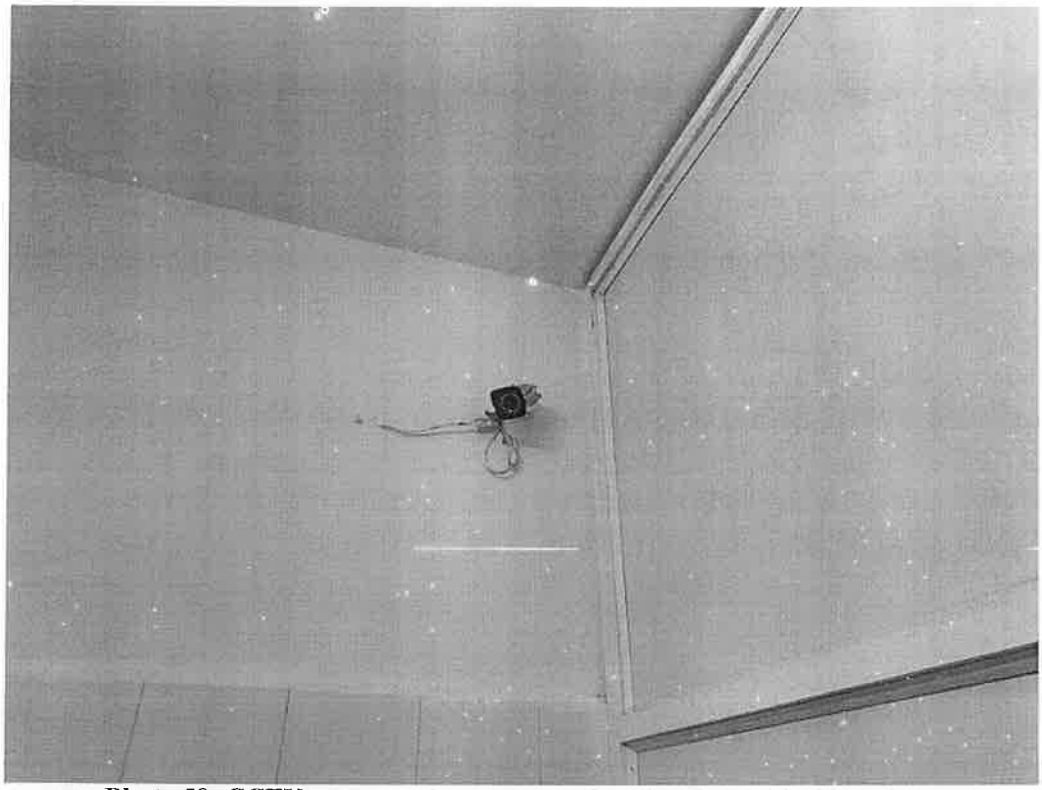


Photo 58: CCTV cameras absent or non-functional at critical locations

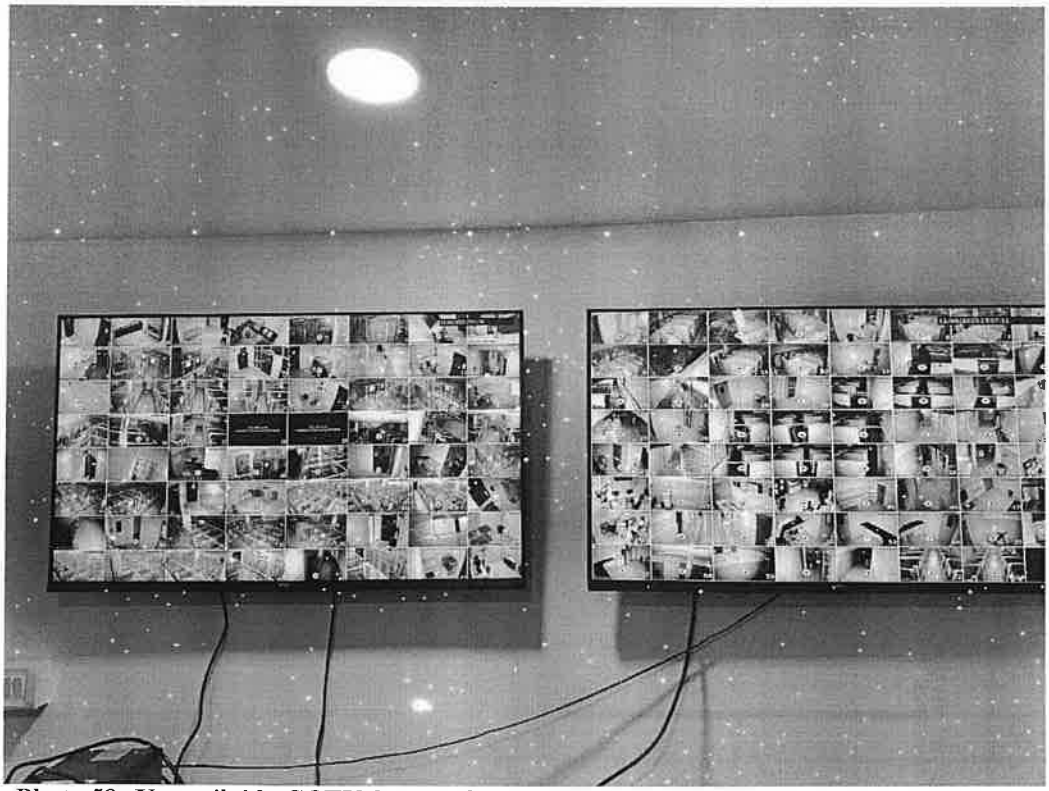
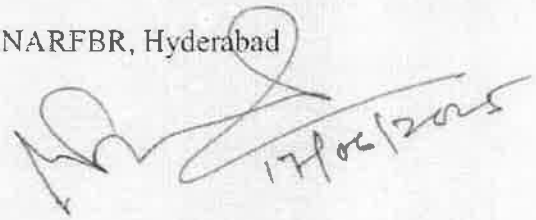


Photo 59: Unavailable CCTV footage from critical areas raises transparency concerns

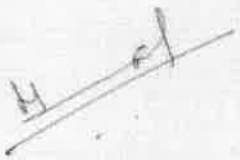
Inspection Team Signatures and Verification

We, the undersigned members of the inspection team, hereby affirm that the findings, observations, and conclusions presented in this report are accurate to the best of our knowledge, based on the on-site inspection conducted at Palamur Biosciences Pvt. Ltd, on 11 June 2025, and the information made available by PBPL representatives. This report is respectfully submitted to the Committee for the Control and Supervision of Experiments on Animals (CCSEA) for its consideration and appropriate action in accordance with the applicable rules and regulations.

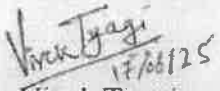
1. Dr. Mukesh Kumar Gupta
   Member, CCSEA & Director, ICMR-NARFBR, Hyderabad



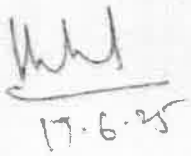
2. Dr. Manilal Valliyate
   Member, AWBI



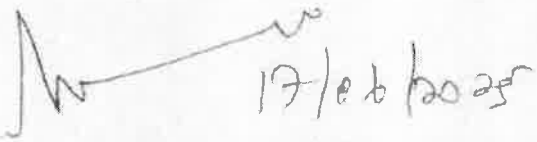
17.06.2025



3. Dr. Vivek Tyagi
   Senior Consultant, CCSEA



4. Dr. B.D.P. Kala Kumar
   Main Nominee, IAEC



5. Shri A. Madhava Rao
   Socially Aware Nominee, IAEC

6. Ms. Alokparna Sengupta
   Managing Director, Humane World for Animals India Foundation

Annexure 2:

FDA warning letter to Palamur Biosciences Pvt. Ltd.

WARNING LETTER

Palamur Biosciences Private Limited

MARCS-CMS 708579 — DECEMBER 11, 2025

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Product:

Medical Devices

Recipient:

S. Ramamoorthy, Ph.D.
Chief Executive Officer (CEO)
Palamur Biosciences Private Limited
Boothpur Mandal
Mahabubnagar 509382 Telangana
India

ram.murthy@palamurbio.com (mailto:ram.murthy@palamurbio.com)

Issuing Office:

Center for Devices and Radiological Health
United States

WARNING LETTER

December 11, 2025

Dear Dr. Ramamoorthy:

This Warning Letter is to inform you of objectionable conditions observed during the United States Food and Drug Administration (FDA) inspection conducted at Palamur Biosciences Private Limited (PBS) from January 20, 2025, to January 27, 2025, by investigators from the FDA's Office of Bioresearch Monitoring Inspectorate (OBMI) Foreign Inspection Cadre. This inspection was conducted to determine whether activities and procedures related to your participation in Good Laboratory Practice (GLP) nonclinical studies complied with applicable federal regulations. Specifically, FDA investigators focused on the list of studies below including, but not limited to, implantation, acute systemic toxicity, material mediated pyrogenicity (MMP), and guinea pig maximization tests conducted at your facility.

The list of studies below is not an all-inclusive list of studies impacted by the inspection or by the violations cited in this letter.

Study number	Test

231918	Implantation Study
24636	Implantation Study
231192	Acute Systemic Toxicity
231165	Acute Systemic Toxicity
231809	Acute Systemic Toxicity
231868	Acute Systemic Toxicity
24085	Acute Systemic Toxicity
24110	Acute Systemic Toxicity
24005	MMP
24084	MMP
24378	MMP
231866	Guinea Pig Maximization Test
231586	Guinea Pig Maximization Test
231191	Intracutaneous Reactivity
231196	In Vitro Cytotoxicity

These tests are used in nonclinical studies for the development of devices as that term is defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h)(1), because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemption, Premarket Approval applications, and Premarket Notification submissions are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the OBMI revealed serious violations of Title 21, Code of Federal Regulations (CFR) Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies, which concerns, among other things, requirements prescribed under section 520(g) of the Act, 21 U.S.C. § 360j(g). Compliance with Part 58 is intended to assure the quality and integrity of the safety data filed in a premarket submission. At the close of the inspection, the FDA investigators presented an inspectional observations Form FDA-483 for your review and discussed the observations listed on the form with you.

We received the initial response from your firm dated February 17, 2025, concerning our investigators' observations noted on the Form FDA-483. We have since received follow-up responses to the initial response from your firm on the following dates:

- April 13, 2025
- May 12, 2025
- July 8, 2025
- August 12, 2025
- September 16, 2025

This letter discusses your written responses to the noted investigators' observations and requests prompt corrective action to address violations of 21 CFR Part 58. These violations include, but are not limited to, the following:

1. Failure of the study director to assure that all experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified [21 CFR 58.33(b)].

The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control. The study director's responsibilities include ensuring that all experimental data are accurately recorded and verified. Examples of the study director's failures to adhere to this requirement include, but are not limited to, the following:

a. For study 231918, the Animal/Bird Requisition and Issuance Record shows that the rabbits were 7-8 months old, but the breeding records do not include birth dates. Additionally, the animals were only given identification (R1 through R12) when they were enrolled in and throughout the study, and this identification cannot be traced back to the Animal Issue Record maintained by the Animal Breeding and Husbandry (ABH) department. The Animal Issue Record lists species/strain, sex, age range and body weight range for a group of rabbits issued for a particular study. However, there are no medical records associated with the individual rabbits and no way of verifying the accurate age of each animal. Because animal age can impact the analysis and interpretability of test results, it is important that the age of each animal in a study is accurately recorded and can be verified.

b. The raw study data for the acute systemic toxicity studies (231192, 231165, 231809, 231868, 24085, and 24110) and MMP studies (24005, 24084, and 24378) did not have the rate of intravenous administration of the bolus in each animal recorded. Additionally, the start and end time of intravenous injection are not recorded. Study plans for all acute systemic toxicity and MMP studies require that intravenous injections be administered consistent with the guidelines outlined in the International Organization for Standardization (ISO) 10993, Biological Evaluation of Medical Devices, and/or the United States Pharmacopeia (USP) Chapter 151, Biological Tests – Pyrogen Test, as applicable. The rates of intravenous injections were not recorded; therefore, it cannot be verified whether these tests were conducted according to the testing guidelines.

c. For study 24636, there were no records of physical examinations of Guinea Pigs 1 through 12 upon receipt of the animals from the vendor, upon release from quarantine, or before the surgical procedure. The health of the animals was not comprehensively examined and recorded at the start of the study and anesthesia status was not assessed before the surgical procedure. Therefore, it cannot be confirmed whether the animals were healthy or showing any abnormal clinical signs. Clinical observations are important to record for the reliability of the subsequent analysis of the responses of the animal to the test article, as well as for evaluating whether the animal needs any treatment or intervention.

As the principal point of study control, the study director did not ensure that all experimental data were accurately recorded and verified, which in turn yields questionable study results. Based on this failure, the FDA has concerns about the quality and integrity of data generated from the nonclinical laboratory studies conducted at your testing facility. Complete and

accurate study data are necessary to allow FDA to fully assess the overall safety and risk of a device with an associated premarket submission. The unreliable data raises concerns about the quality and integrity of associated premarket submissions, which may put public health and safety at risk.

Your written responses are inadequate. The written responses provided revised standard operating procedures (SOPs), forms, and staff training records, but they do not include any planned preventive actions such as frequency (e.g., quarterly, annual) of audits to check for compliance or future training for new staff and/or new procedures. Additionally, while you provided a copy of the form, PRM/PBS/TOX/014, “Animal/Bird Requisition and Issuance Record” as evidence of the health status of the animals, the form lacks detailed documentation of physical examinations conducted by qualified personnel (e.g. veterinarian). Furthermore, while your responses propose corrections for the specific observations noted, you have not indicated whether any systematic reviews of your procedures will be conducted to identify and correct any systemic issues. Your explanation, when taken into consideration with the violations described above, which occurred in multiple studies, suggests systemic failures in study director oversight of nonclinical laboratory studies and brings into question the quality and integrity of safety data collected at your testing facility. Thus, your responses do not provide assurance that similar violations would not occur again.

2. Failure of the testing facility to have standard operating procedures in writing setting forth nonclinical laboratory study methods that management is satisfied are adequate to ensure the quality and integrity of the data generated in the course of a study. [21 CFR 58.81(a)].

SOPs should be adequate to ensure the quality and integrity of data generated in a study. However, not all SOPs appear to be adequate. Examples of your failures to adhere to this requirement include, but are not limited to, the following:

a. SOP/PBS/TOX/001, Recording of Body Weight and Procedure for Feed and Water Consumption, does not include procedures for calibration of the balance used for weighing animals. Section 5.1 of the SOP states that, “[t]he balance will be set and calibrated as specific to the balance in use.” However, there is no specific information as to who is responsible for calibration (e.g., study personnel assigned to each study) or when calibration should be performed (e.g., whether the calibration should be performed prior to body weight measurement or whether it should be performed at specific dates/intervals).

b. SOP/PBS/GEN/047, Sample and Reference Material Preparation for Biological Evaluation of Medical Devices, does not include detailed procedures for extraction depending on the test article (e.g., test articles indicated for prolonged or long-term tissue contact may require different extraction conditions than those with limited contact). Additionally, the SOP does not provide detailed instructions for monitoring of changes in the color of the test extract. Sample preparation is one of the crucial steps in biocompatibility testing of medical devices. Conditions of medical device extraction, such as extraction temperature, duration of extraction, and vehicle use can significantly impact the outcomes of a biocompatibility study.

c. SOP/PBS/PAT/012, Euthanasia of Laboratory Animals/Birds, does not contain sufficiently detailed procedures for administration of carbon dioxide (CO2) for inhalation euthanasia for rodents to fulfill the objective of rapid unconsciousness with minimal distress to the animals. For example, the SOP does not contain information about the settings of the flowmeter for the delivery of the CO2 gas or include specific procedures for using CO2 inhalation in rodents.

Failure of a testing facility to have adequate SOPs raises questions about the reliability and accuracy of the data and does not ensure the quality and integrity of data generated in a study. Inadequate SOPs yield inadequate protocols that introduce ambiguity and uncertainty as to how study requirements are to be followed, as well as inconsistent execution of studies and unreliable study results. Inadequate SOPs could result in study data with a high level of variability that challenges the ability to effectively interpret the study results associated with a device. This in turn adversely impacts a manufacturer’s and FDA’s ability to assess the overall safety and risk of the subject device prior to use in humans as a legally marketed device or for purposes of beginning clinical trials.

Your written responses are inadequate. The responses provided revised SOPs, forms, and staff training records, but they do not: (1) detail how your testing facility will ensure that applicable SOPs will be followed to ensure the quality and integrity of data generated in a study; and (2) address any planned preventive actions, such as frequency (e.g., quarterly, annual) of audits to check for compliance or future training for new staff and/or new procedures. Additionally, while your responses propose corrections for the specific observations noted, you have not indicated whether any systematic reviews of your procedures will be conducted to identify and correct any systemic issues, including ensuring that there are existing SOPs that cover all relevant functions, as well as ensuring that all SOPs are sufficiently detailed to allow personnel to correctly perform these functions. Thus, your written responses do not provide assurance that similar violations would not occur again.

3. Failure of the testing facility management to assure that personnel clearly understand the functions they are to perform [21 CFR 58.31(f)].

An example of the testing facility management's failure to adhere to this requirement includes, but is not limited to, the following:

a. For Guinea Pig Maximization Test (GPMT) study 24838, the study personnel failed to identify and record adverse tissue responses to the injected adjuvant and clinical observations (e.g., difficulty breathing). SOP/PBS/TOX/008 indicates that after intradermal induction, skin reactions such as edema, erythema, and necrosis, along with other clinical signs will be recorded. However, the records that were reviewed did not indicate that clinical signs were recorded. In addition, there is no procedure that describes what clinical signs should be assessed to determine the health of the animal or how the technician would recognize skin reactions and distinguish between similar responses (e.g., between a "discrete" and "moderate" skin reaction). Furthermore, it was observed that study personnel training does not include species-specific in-life observations and when veterinarian oversight should be requested.

Failure of testing facility management to assure that all personnel clearly understand the functions they are to perform and are adequately qualified and trained creates a high level of variability that does not ensure the validity and quality of the data. Personnel that do not clearly understand the functions they are to perform cannot consistently perform tasks according to the SOPs. This can have a negative impact on a study and calls into question the quality and integrity of studies conducted at your testing facility.

Your written responses are inadequate. Your responses included revised SOPs, training records, and creating a new division for Ethology & Animal Welfare to focus on clinical sign observation, ethology, animal welfare training, and enrichment, in addition to appointing a technical consultant to assist with personnel training. However, it is not clear what oversight for the new head of Ethology and Animal Welfare will entail or what technical expertise will be provided by the technical consultant. Furthermore, your responses do not address planned preventive actions, such as frequency (e.g., quarterly, annual) of audits to check for compliance or future training for new staff and/or new procedures. Additionally, while your responses propose corrections for the specific observations noted, you have not indicated whether any systematic reviews of your training program will be conducted to identify and correct any gaps in personnel training. Furthermore, while you have provided training records containing quizzes that test personnel's recollection of the training received, you have not described how personnel's ability to perform the tasks in question will be assessed to ensure that the training achieves its intended goal. Thus, your written responses do not provide assurance that similar violations would not occur again.

4. Failure of the Quality Assurance Unit (QAU) to determine that no deviations from approved protocols or SOPs were made without proper authorization and documentation [21 CFR 58.35(b)(5)].

The QAU is responsible for determining that no deviations from approved protocols or SOPs were made without proper authorization and documentation. An example of the QAU's failures to adhere to this requirement includes, but is not limited to, the following:

a. For study 231918, the study plan stated that the rabbits should have a supraglottic airway device inserted; however, the surgical records showed that an endotracheal tube was used for delivery of inhalant anesthesia. There is no record to indicate that this deviation was identified by the QAU, and there is no documentation to indicate that this deviation was made with proper authorization.

A reliable QAU is integral to the successful understanding and completion of any GLP study. Without appropriate QAU oversight, neither the sponsor nor FDA reviewers have assurance that the data in the final study report is accurate and valid. Failure to perform QAU functions can have a negative impact on a study and calls into question the quality and integrity of studies conducted at your testing facility.

Your written responses are inadequate. Your written responses include generating a record of an SOP deviation, performing a root cause analysis, and opening a corrective and preventative actions plan. However, your responses do not detail planned preventive actions, such as frequency (e.g., quarterly, annual) of audits to check for compliance of the QAU or future training for new staff and/or new procedures. Additionally, while your responses propose corrections for the specific observations noted, you have not indicated whether any systematic reviews of your QAU will be conducted to identify and correct any systemic issues.

In addition to the device studies described above, FDA investigators also observed that your facility performs studies intended to support the approval of new animal drugs. The overall conditions and practices at your facility, as exemplified above, may impact the validity and integrity of the data obtained to support new animal drug applications. For example, in study 19278, your records indicate you centrifuged the majority of blood samples before they were actually collected. In your response, you indicated you were unable to reconstruct what happened. This calls into question the quality and integrity of data generated from the nonclinical laboratory studies conducted at your testing facility. You should ensure that you consider animal drug studies as part of your corrective and preventive actions.

FDA investigators also observed that the exterior of the testing facility had significant accumulations of dirt, animal droppings, and potential pest harborage. Upon inspection of Block F, the HVAC equipment on the outside of the building was found to be surrounded by a large amount of dirt and debris that could attract and provide harborage for various pests and could potentially be caught up in the HVAC equipment, possibly causing failure. Such conditions may impact nonclinical studies conducted at your facility.

The violations described above are not intended to be an all-inclusive list of problems that may exist with your facility. It is your responsibility as a nonclinical laboratory to ensure compliance with the Act and applicable regulations.

Within 15 working days of receiving this letter, please provide documentation of the additional corrective and preventive actions that you have taken or will take to correct these violations and to prevent the recurrence of similar violations in current or future studies for which you are the testing facility. Any submitted corrective action plan should include projected completion dates for each action to be accomplished as well as a plan for monitoring the effectiveness of your corrective actions. In addition, please provide a complete list of all nonclinical laboratory studies of FDAregulated devices for the last five years, including the name of the study, the test article, the name of the study director and sponsor, and the current status of the study. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you. In addition, FDA could initiate disqualification proceedings against you in accordance with 21 CFR 58.202. If you believe that you have complied with the Act and FDA regulations, please include your reasoning and any supporting information for our consideration.

Your response should reference “CTS# EC250128/E001” and be sent via email to: Irfan.Khan@fda.hhs.gov.

A copy of this letter has been sent to FDA’s OBMI Foreign Inspection Cadre via email at FDAInternationalBIMO@fda.hhs.gov. Please send a copy of your response to that office.

If you have any questions, please contact Amrin Chowdhury by phone at (240) 402-8318 or email at Amrin.Chowdhury@fda.hhs.gov.

Sincerely yours,
/S/

Ouided Rouabhi, MS
Acting Director
DCEA1: Division of Clinical Policy and Quality
Office of Clinical Evidence & Analysis
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Annexure 3:

Comparative analysis between the findings of the 17 June 2025 CCSEA inspection report with the FDA's 11 December 2025 Warning Letter

Comparison Matrix:

U.S. Food and Drug Administration (FDA) Warning Letter (11 Dec 2025) vs Committee for the Purpose of Control And Supervision of Experiments on (CCSEA) Inspection Report (Submitted 17 June 2025) on Palamur Biosciences Private Limited (PBPL)

The US FDA's warnings are in relation to the reliability and integrity of experimental data, while CCSEA's commissioned expert report is largely focused on animal welfare, but as the below chart shows, there is considerable corroboration of findings and overlap as poor animal welfare also generally translates to unreliable experimentation outcomes, which puts public health at risk. The quotes are verbatim from the US FDA warning letter dated 11 December 2025 and the CCSEA-commissioned inspection report submitted on 17 June 2025.

Key summary language has been bolded by PETA India for ease of the reader.

CCSEA 17th June report: "**The inspection team concluded that many of the allegations raised by PETA India's whistle-blower-including overcrowding, veterinary neglect, inappropriate handling, and euthanasia violations-were substantiated** or could not be conclusively refuted due to the absence of required documentation."

Grounds	FDA warning letter-verbatim	CCSEA 17th June 2025 report-Verbatim
Systemic Nature of Violations	"**The violations described above… occurred in multiple studies, suggests systemic failures** in study director oversight of nonclinical laboratory studies and brings into question the quality and integrity of safety data collected at your testing facility." "As the principal point of study control, the study director did not ensure that all experimental data were accurately recorded and verified, which in turn yields questionable study results. Based on this failure, the FDA has concerns about the quality and integrity of data generated from the nonclinical laboratory studies conducted at your testing facility…**The unreliable data raises concerns about the quality and integrity of associated premarket submissions, which**	"**The inspection revealed serious and widespread non-compliance with CCSEA regulations.** Key welfare violations included **overcrowded and barren kennels, lack of environmental enrichment, feeding practices not aligned with the animals' physiological needs and body weight requirements, untrained and rough handling practices, and an alarming absence of protocols for pain management, sedation, and euthanasia. Veterinary infrastructure was critically inadequate**, with poor medical coverage, minimal drug availability, and no functioning isolation or quarantine facilities."

	may put public health and safety at risk." "Thus, **your responses do not provide assurance that similar violations would not occur again**."	"**The operational deficiencies observed at PBPL are not isolated incidents but indicative of entrenched structural, procedural, and ethical failures.** The scale and severity of non-compliances documented during the inspection raise significant concerns regarding the facility's adherence to established standards of animal welfare and regulatory accountability. **The situation demands urgent attention—particularly with respect to the removal and rehabilitation of animals** to prevent further pain, distress, or suffering. **The findings also call for a critical review of the facility's registration and breeding licence**, in view of the serious and repeated deviations from prescribed norms." "Overall, **the findings reflect a systemic and ongoing disregard for regulatory compliance, ethical responsibility, and animal welfare.**" "[T]he conditions observed at PBPL point to **substantial deficiencies in veterinary access, preventive healthcare, and critical welfare infrastructure**. These shortcomings compromise both the physical well-being and dignity of the animals and present serious ethical and regulatory concerns that warrant urgent attention."

Violation of Law, Procedure and Guidelines	"Our review of the inspection report prepared by the OBMI revealed **serious violations of Title 21, Code of Federal Regulations (CFR) Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies**, which concerns, among other things, requirements prescribed under section 520(g) of the Act, 21 U.S.C. § 360j(g)."	"The comprehensive inspection of PBPL highlights **systemic failures at multiple levels of its operations to uphold animal ethics and welfare as per CCSEA guidelines**. PBPL's approach to animal research demonstrates an operational model that prioritizes experimental output over welfare, compliance, and ethical responsibility. Despite its extensive use of dogs, non-human primates, pigs, and other species, **PBPL has failed to implement even the most basic standards of care mandated by CCSEA**."
Failure of Adequate Record-Keeping—Creating a Lack of Reliability on Compliance, Animal Welfare and Quality of Experiments	"[T]here are no medical records associated with the individual rabbits and no way of verifying the accurate age of each animal. Because animal age can impact the analysis and interpretability of test results, it is important that the age of each animal in a study is accurately recorded and can be verified." "The raw study data for the acute systemic toxicity studies (231192, 231165, 231809, 231868, 24085, and 24110) and MMP studies (24005, 24084, and 24378) did not have the rate of intravenous administration of the bolus in each animal recorded. Additionally, the start and end time of intravenous injection are not recorded…The rates of intravenous injections were not recorded; therefore, it cannot be verified whether these tests were conducted according to the testing guidelines."	"The animal record-keeping system at PBPL is virtually non-functional, with key regulatory documentation either missing or grossly insufficient. Without breeding records, reuse data, health histories, or procedural logs, PBPL operates in opaque conditions that obstruct regulatory oversight." "PBPL failed to provide any documentation detailing the number, age, sex or species-wise inventory of animals held or used at the facility, despite repeated requests." "The absence of on-site veterinary records further prevented verification of health screenings, disease status, or any actions taken regarding zoonotic diseases." "[Records] fail to provide any comprehensive overview of essential information such as the

	“For study 24636, there were no records of physical examinations of Guinea Pigs 1 through 12 upon receipt of the animals from the vendor, upon release from quarantine, or before the surgical procedure. The health of the animals was not comprehensively examined and recorded at the start of the study and anesthesia status was not assessed before the surgical procedure. Therefore, it cannot be confirmed whether the animals were healthy or showing any abnormal clinical signs.”	total number of animals used, the frequency of their use in experiments, clinical conditions identified, or the preventive and therapeutic care administered-whether at the breeding facility or the experimentation centre. This fragmented and superficial record-keeping reflects a seriously negligent approach to both regulatory compliance and animal welfare standards. Moreover, veterinary records were not available on-site, significantly hampering the ability to conduct thorough inspections or continuous assessments of animal health and well-being. Without access to these records, it is impossible to monitor medical histories, vaccination status, or previous treatments--elements that are vital to ensuring timely and appropriate veterinary care. The absence of a structured, accessible veterinary documentation system undermines the facility's responsibility to safeguard the animals in its custody.” “A critical gap lies in the absence of a functional system for recording preventive healthcare and treatment interventions. No accessible, structured on-site veterinary documentation was available, and existing loose case sheets are reportedly stored in a separate building-severely limiting timely medical assessments and ongoing veterinary oversight. This lack of accessible records undermines

		the ability to monitor animal health, track vaccination and treatment histories, or assess compliance with humane care and regulatory norms."
Inadequate SOPs and Lack of Discipline in Experimental Procedures Resulting in Cruelty to Animals and Unreliable Experiments	"[N]not all SOPs appear to be adequate." "SOP/PBS/TOX/001, Recording of Body Weight and Procedure for Feed and Water Consumption, does not include procedures for calibration of the balance used for weighing animals. Section 5.1 of the SOP states that, '[t]he balance will be set and calibrated as specific to the balance in use.' However, there is no specific information as to who is responsible for calibration (e.g., study personnel assigned to each study) or when calibration should be performed (e.g., whether the calibration should be performed prior to body weight measurement or whether it should be performed at specific dates/intervals)." "b. SOP/PBS/GEN/047, Sample and Reference Material Preparation for Biological Evaluation of Medical Devices, does not include detailed procedures for extraction depending on the test article (e.g., test articles indicated for prolonged or long-term tissue contact may require different extraction conditions than those with limited contact). Additionally, the SOP does not provide detailed instructions for monitoring of changes in the color of the test extract. Sample preparation is one of the crucial steps in biocompatibility testing of medical devices. Conditions of medical device extraction, such as	"[A] clear inconsistency was observed between the number of CCSEA-approved research protocols-reported to be 87 over the past three months-and the actual number of dogs, minipigs and monkeys present at the facility. This discrepancy suggests possible non-compliance with approved study limits or underreporting of animal populations." "Crucially, the mandatory three-month washout period-required to ensure complete elimination of substances from animals' systems before reuse-was reportedly not being followed, particularly for rninipigs. No documentary evidence was produced during the inspection to verify compliance with this requirement. This lapse not only violates standard ethical and scientific guidelines but also compromises the validity of subsequent research and the welfare of the animals involved." "Contrary to the mandates set forth by CCSEA regulations and guidelines, a case study based on data from the software application used at PBPL's experimentation facility revealed serious lapses in animal welfare. In one instance, a dog exhibiting mild to moderate tremors was not withdrawn from the

	extraction temperature, duration of extraction, and vehicle use can significantly impact the outcomes of a biocompatibility study." "Failure of a testing facility to have adequate SOPs raises questions about the reliability and accuracy of the data and does not ensure the quality and integrity of data generated in a study. Inadequate SOPs yield inadequate protocols that introduce ambiguity and uncertainty as to how study requirements are to be followed, as well as inconsistent execution of studies and unreliable study results. Inadequate SOPs could result in study data with a high level of variability that challenges the ability to effectively interpret the study results associated with a device. This in turn adversely impacts a manufacturer's and FDA's ability to assess the overall safety and risk of the subject device prior to use in humans as a legally marketed device or for purposes of beginning clinical trials."	experiment. The symptoms reportedly progressed to severity and became severe by the tenth day. The animal was then marked as 'removed' and 'killed-moribund' on the twelfth day. The terminology used in the software-'removal' and 'killing-moribund'-is ambiguous and fails to clarify whether any action was taken to alleviate the animal's suffering during this period. As per regulatory guidelines, an animal exhibiting significant neurological symptoms such as tremors, indicative of high drug toxicity, should be promptly removed from the study and provided with appropriate medical intervention. In this case, both the researcher and the clinical veterinarian failed to take timely action. Moreover, the software did not provide any detailed account of the animal's clinical parameters, additional symptoms, or medications administered. Although the clinical veterinarian claimed that such records were maintained on loose sheets using a fixed format, she was unable to produce the relevant documentation even after an extensive search. This raises serious concerns about the absence of evidence-based health monitoring or treatment interventions at PBPL."

		"The veterinary logs, maintained as loose case sheets, lack essential clinical details-such as observed clinical signs, diagnostic assessments, and medications administered. This incomplete and inconsistent documentation renders the recording system ineffective, offering no tangible benefit to the animals' health, treatment, or ongoing care."
Unauthorised Frequent Reuse of Animals for Experiments		"PBPL failed to demonstrate how many times individual animals were reused-a practice that requires specific approval from the CCSEA" "The inspection team was informed that animals across all species are reused in multiple experiments, including pharmacokinetic and toxicological studies. In the case of dogs and minipigs, it was claimed that a three-year usage period is followed, with intermittent 'washout period' of one month between experimental uses. However, no written policy documents, institutional protocols, or Standard Operating Procedures (SOPs) were provided to substantiate this claim. Practising a one-month 'washout period' is a violation of CCSEA guidelines for reuse/rehabilitation of large animals post experimentation (2020), which mandates a minimum of three months as a 'washout period'.

		It was conveyed that pharmacokinetic studies generally involve repeated use of the same animal, whereas toxicological studies are usually conducted only once per animal. The CCSEA guidelines for reuse/rehabilitation of large animals post experimentation (2020) mandate that animals showing liver or kidney impairment, within the three-year period, cannot be reused, and the detailed health status of all such animals shall be maintained in a prescribed format. However, in the absence of accessible records, there was no way to independently verify these practices."
Lack of Pain and Anxiety Management		"There was no protocol in place to address anxiety, fear, or psychological distress in animals-highlighting a grave neglect of mental welfare, and a veterinary protocol grossly failing to meet even the minimum required standards for the prevention of unnecessary suffering." "In a recent invasive experiment on two monkeys involving surgical implantation and daily wound care, only analgesics were used post procedure, with physical restraint applied without sedatives-indicating serious neglect of psychological welfare. Similarly, dogs euthanised at the end of research studies were not sedated prior to the administration of thiopentone sodium. These practices highlight critical flaws in the

		veterinary protocol, failing to meet even the basic standards for preventing unnecessary pain and suffering."
Lack of Suitable Veterinary Care, Infrastructure & Medicinal Stock		"[T]here was a complete absence of essential infrastructure-no dedicated quarantine areas, no isolation wards for sick animals, and no grooming or exercise facilities. This was consistent across all large animal species, including monkeys, dogs, sheep, minipigs, and pigs, and represents a systemic failure to uphold even the minimum standards of animal welfare." "The overall approach to animal welfare and veterinary care at PBPL, reflects a deeply troubling lack of commitment to the health and well-being of the animals in its custodv. The organisation appears to function primarily as a client-facing entity, with minimal regard for fundamental animal welfare principles, including the prevention of unnecessary pain, suffering, and distress." "Veterinary care infrastructure was deeply inadequate. The facility maintained minimal medical supplies, lacked essential analgesics, sedatives, and anaesthetics, and failed to maintain proper treatment records. Notably, no protocol was in place to manage anxiety, fear, or distress-an essential component of humane animal care. Painful and invasive procedures, such as those performed on monkeys involving surgical implantation,

		were conducted using only analgesics post procedure, with animals physically restrained without sedatives. Similarly, dogs euthanised at the conclusion of research were not sedated before the administration of thiopentone sodium. These practices reflect glaring omissions in veterinary planning and a disregard for psychological well-being." "Despite conducting procedures that are invasive or likely to cause physical and psychological distress, the clinical examination areas adjacent to the experimentation rooms were found to be unequipped with basic medical kits. Furthermore, the medical inventory lacked essential sedatives, analgesics, and anaesthetics-key components for preventing unnecessary pain and suffering in animals. No consolidated treatment records were maintained to document either pain recognition or pain management." "The medical inventory maintained by PBPL is grossly inadequate for a facility housing over 1,500 animals across various species. The central store contained only limited quantities of basic medications such as dewormers, multivitamins, and mineral supplements. Critically, there was no stock of essential medications such as sedatives, analgesics, or anaesthetics, raising grave concerns about the

		facility's ability to manage anxiety, fear, distress, pain, perform safe medical procedures, or carry out ethical clinical care. While the experimentation room includes a clinical veterinarian and an examination table, there were no emergency or pain-management medicines available at the site for immediate intervention. This further reinforces the perception that PBPL's role is largely confined to conducting studies that culminate in euthanasia, necropsy, and histopathological examination, rather than ensuring ongoing health and welfare." "Critically, both the breeding and experimentation centres lack essential veterinary medicines, including those necessary for emergency care, pain relief, or disease prevention. In the absence of these fundamental medical supplies, veterinarians are effectively unable to provide any meaningful treatment or alleviate unnecessary pain and suffering. As a result, there is no 24x7 functional veterinary system in place to safeguard the health and welfare of the large number of animals currently housed at PBPL."
Poor Quarantine, Disease Screening and Separation of Healthy and Sick Animals		"There was a total absence of dedicated quarantine rooms and isolation rooms for sick animals, which critically compromises biosecurity and disease management."

		“Across all facilities, it was reported that individual cages within shared housing rooms are being used as makeshift quarantine and isolation spaces. This practice falls far short of accepted quarantine protocols and fails to provide the critical separation needed to prevent cross-contamination. The absence of proper quarantine infrastructure in a facility housing over 1,500 animals reflects a serious disregard for both animal and human health and welfare. This concern is further exacerbated by the lack of on-site veterinary records, making it impossible to verify health screenings, disease surveillance, or any measures taken to address zoonotic risks.” “Several dogs from the breeding stock were found housed in two experimental facilities due to insufficient space in the designated breeding area- highlighting poor planning and inadequate resource management. Critically, these animals had not been screened for disease conditions prior to relocation, despite such screening being a mandatory prerequisite before introducing animals into experimental zones. This oversight raises serious concerns regarding contamination risks and compromised sterilisation standards. Additionally, some dogs were reportedly transferred for experimental procedures without visible tags or

		identifiers, making it impossible to trace individual histories or monitor their use--constituting a serious violation of standard compliance protocols." "PBPL informed that the current screening protocol for monkeys does not include Kyasanur Forest Disease (KFD)-a zoonotic infection known to be prevalent among monkeys in India. Considering that the monkeys are wild-caught, and in view of the potential biosecurity implications and associated health risks for researchers and staff, including KFD in the screening process would be a prudent and proactive measure."
Cruelty During Euthanasia Procedures	"SOP/PBS/PAT/012, Euthanasia of Laboratory Animals/Birds, does not contain sufficiently detailed procedures for administration of carbon dioxide (CO2) for inhalation euthanasia for rodents to fulfill the objective of rapid unconsciousness with minimal distress to the animals. For example, the SOP does not contain information about the settings of the flowmeter for the delivery of the CO2 gas or include specific procedures for using CO2 inhalation in rodents."	"The inspection also uncovered troubling deviations from approved euthanasia protocols. Animals were euthanised without sedation, relying solely on physical restraint-a practice incompatible with ethical norms of humane care." "The attending veterinarian confirmed that no sedatives are administered prior to euthanasia to mitigate fear, anxiety, or distress. Instead, thiopentone is injected slowly while an assistant physically restrains the animal-an approach the veterinarian himself acknowledged he would not use if the procedure were a routine surgery such as spaying or castration, or if the breed were less docile, such as a Bulldog,

		Dobermann, or Rottweiler. This underscores a troubling reliance on the naturally gentle and submissive temperament of Beagle dogs, which makes them easier to handle and restrain, even under distressing conditions, without adequate measures to reduce suffering." "Accidental pregnancy led to euthanasia of 8-I 0 piglets via intracardiac injection without prior sedation."
High Kill Rate & Only Performative Rehabilitation		"According to both records and the veterinarian in charge, approximately 30-40 dogs are euthanized each month." "The sheer number of euthanasia cases also suggests that a significant proportion of the animal population is being killed as part of experimental protocols. This may further explain why only 73 dogs were found in the rehabilitation section-a number that appears disproportionately low relative to the reported usage and turnover." "It was observed that the so-called 'rehabilitation area' appeared to be a makeshift arrangement, with a fresh paper label affixed to the door designating it as such. The space itself was evidently an experimental room repurposed as a rehabilitation unit, with no meaningful changes made to accommodate the specific needs of animals undergoing recovery. The environmental conditions

		infrastructure, routine practices, and personnel remained consistent with those of a laboratory setting raising serious concerns about the adequacy, appropriateness and sincerity of the rehabilitation process." "The environment was entirely artificial, with no access to natural light and fully temperature-controlled conditions. The flooring consisted of hard perforated polymer flooring with integrated drainage, which may cause discomfort, offering no physical comfort for the animals to stand, sit, or lie down for long periods. Critically, there was no provision for socialisation, environmental enrichment, or access to outdoor spaces-elements essential for the physical and psychological recovery of rehabilitating animals. The facility, as observed, fell significantly short of providing a conducive, humane, and restorative environment-undermining the very essence of what true rehabilitation should represent." "Dogs are currently rehabilitated within PBPL's own facility. No records were made available to the inspection team indicating that animals had been transferred to AWEI-recognised animal welfare organisations. Additionally, there was no documentation provided regarding any Memoranda of Understanding (MoUs) or financial support extended to

		such organisations for the long-term care of the animals." "The high euthanasia rate suggests an unsustainable use pattern where large numbers of animals are systematically killed after experimental use, with limited rehabilitation or rehoming efforts."
Untrained, Uncaring or Incompetent Personnel Negatively Impacting Animal Welfare & Experimentation Results & Poor Veterinary Oversight	"For Guinea Pig Maximization Test (GPMT) study 24838, the study personnel failed to identify and record adverse tissue responses to the injected adjuvant and clinical observations (e.g., difficulty breathing). SOP/PBS/TOX/008 indicates that after intradermal induction, skin reactions such as edema, erythema, and necrosis, along with other clinical signs will be recorded. However, the records that were reviewed did not indicate that clinical signs were recorded. In addition, there is no procedure that describes what clinical signs should be assessed to determine the health of the animal or how the technician would recognize skin reactions and distinguish between similar responses (e.g., between a "discrete" and "moderate" skin reaction). Furthermore, it was observed that study personnel training does not include species-specific in-life observations and when veterinarian oversight should be requested. Failure of testing facility management to assure that all personnel clearly understand the functions they are to perform and are adequately qualified and trained creates a high level of variability that does not ensure the validity and	"A serious welfare concern was observed when an animal handler lifted a heavy dog by the scruff and used a wiper to move the animal-an act carried out openly in front of the inspection team. The casual manner in which this was done suggests that such rough handling is a routine and accepted practice at PBPL. These actions are inappropriate and raise grave concerns about staff training, supervision, and basic regard for animal welfare." "Of the four veterinarians reportedly assigned to 13 experimental facilities, only two were present at the time of inspection-raising serious concerns about the adequacy of veterinary coverage and timely access to care. In the absence of regular veterinary supervision, dedicated treatment spaces, and structured welfare protocols, animals remain at significant risk of untreated medical issues and unnecessary suffering." "Veterinary care at PBPL is available only between 9:00 a.m. and 5:30 p.m., with no

	quality of the data. Personnel that do not clearly understand the functions they are to perform cannot consistently perform tasks according to the SOPs. This can have a negative impact on a study and calls into question the quality and integrity of studies conducted at your testing facility."	veterinarian coverage during night hours."
Unapproved Deviations from SOPs and Failures of the Quality Assurance Unit (QAU)	"For study 231918, the study plan stated that the rabbits should have a supraglottic airway device inserted; however, the surgical records showed that an endotracheal tube was used for delivery of inhalant anesthesia. There is no record to indicate that this deviation was identified by the QAU, and there is no documentation to indicate that this deviation was made with proper authorization. A reliable QAU is integral to the successful understanding and completion of any GLP study. Without appropriate QAU oversight, neither the sponsor nor FDA reviewers have assurance that the data in the final study report is accurate and valid. Failure to perform QAU functions can have a negative impact on a study and calls into question the quality and integrity of studies conducted at your testing facility." "The overall conditions and practices at your facility, as exemplified above, may impact the validity and integrity of the data obtained to support new animal drug applications."	
Poor Animal Housing, Lack of Enrichment & Filth	"FDA investigators also observed that the exterior of the testing facility had significant accumulations of dirt, animal droppings, and potential pest	"Housing conditions were consistently found to be overcrowded, barren, and inadequate, leading to significant welfare concerns such as

	harborage. Upon inspection of Block F, the HVAC equipment on the outside of the building was found to be surrounded by a large amount of dirt and debris that could attract and provide harborage for various pests and could potentially be caught up in the HVAC equipment, possibly causing failure. Such conditions may impact nonclinical studies conducted at your facility."	elevated stress, noise, poor body condition, and heightened risk of infectious diseases. Essential aspects such as environmental enrichment, social interaction, and proper bedding were either entirely absent or grossly insufficient across all species. The breeding facilities were particularly concerning, with overproduction of animals resulting in unauthorized repurposing of experimental spaces as stock rooms, unscreened animal transfers, and potential biosecurity risks." "Hygrometers installed in the breeding areas showed excessively high relative humidity levels, ranging from 80% to 97%, which can pose serious health risks to the animals."
Unapproved & Unauthorised Animals		"[T]he number of animals observed during the inspection did not align with the facility's declared housing capacity or the volume of CCSEA-approved experimental protocols. The presence of surplus, unscreened stock animals in experimentation rooms points to serious gaps in documentation and oversight." "The headcount and placement of dogs housed at PBPL indicate that the facility is exceeding the number approved by CCSEA, in direct violation of regulatory limits, which is 1000 dogs. This overpopulation appears to stem from breeding activities surpassing the number of animals required for ongoing

		experiments. As a result, two rooms--originally designated for experimentation and located in close proximity to active experimental areas-were repurposed as stock rooms to accommodate the surplus animals. Notably, this was done without screening the dogs for infectious diseases. Veterinarians at the facility stated that the rooms would be fumigated and sterilised before being returned to experimental use, however, even if this is outlined in the organisation's SOPs, reliance on such reactive measures raises concerns regarding the robustness of biosafety protocols." "The overall population of dogs far exceeds CCSEA-approved limits, with multiple species present without adequate disclosure or accurate record-keeping. Critical documentation - including consolidated animal inventories, veterinary treatment records, and breeding logs - was consistently absent, incomplete, or untraceable." "Company purchased Gottingen minipigs but lacked a license to breed them." "An overall high housing density of dogs was observed in the breeding modules, and excess breeding stocks were found to be housed in dog experimental areas." "A noticeable inconsistency was observed between the number of

		CCSEA-approved research protocols and the actual population of minipigs housed, which raises questions regarding breeding."
Animals in Poor Condition and Poor Handling		"None of the dogs in the breeding modules were provided with any form of bedding and were left to lie directly on slippery tiled floors-an inappropriate and uncomfortable surface that fails to meet even the most basic animal welfare requirements." "Dogs in poor body condition, including several exhibiting cherry eye, were observed at the breeding modules. However, due to the absence of consolidated medical records or documentation, there was no evidence of any treatment history or supportive interventions provided for these animals." "General body condition of minipigs appeared poor. However, due to absence of medical records on-site, the health status of minipigs could not be ascertained." "The body condition score of the cows was generally poor, with most animals appearing underweight and below the average standard." "During cleaning, nursing mothers and puppies were reportedly transferred to crates, some of which were found to be

		damaged-posing both hygiene and injury risks to the animals."
Inadequate Nutrition		"[A] single daily feeding is not aligned with standard welfare practices for laboratory-housed dogs, particularly Beagles, which benefit from multiple feedings and enrichment. Thus, the current feeding regime may contribute to nutritional imbalance and does not reflect best practices in animal nutrition and welfare management."
High Noise Levels		"The constant noise from continuous barking created an environment with dangerously high noise levels, indicative of widespread stress and discomfort among the animals. Alarmingly, the facility manager was unable to provide the exact number of dogs housed in the breeding section, and no records were available for verification."
Elaboration of Poor Housing Conditions & Filth		"The kennels in the dog breeding section were generally dirty, soiled with faeces, and poorly maintained. The overall environment of the dog breeding units was uninviting and clearly neglected, reflecting a troubling disregard for the basic care, hygiene, and welfare needs of the animals." "As outlined in the section on housing conditions for animals bred and used in experiments, while the space provided is generally inadequate, the breeding facilities also Jacked proper ventilation and were marked by poor hygiene

		standards. In contrast, the experimental facility showed marginal improvements in air-conditioning and cleanliness; however, fundamental welfare concerns persisted across both settings."
Elaboration of Poor Enrichment & Performative Socialisation Facilities		"[The dogs] were not provided with any outdoor access or designated free time. While facility staff claimed that animals were let out during cleaning, a review of CCTV footage did not show dogs being allowed out for play or exercise, raising doubts about the accuracy of these claims." "No environmental enrichment was provided, except few plastic bones-there were no toys, stimulation objects, or oppmtunities for social interaction. According to staff, the dogs were only let out of their cages during cleaning, indicating a highly restrictive and unstimulating environment with extremely limited chances for exercise or socialisation." "The designated socialisation area for dogs measured approximately 550 square metres, was barren, and had a hard concrete surface. Given that the facility houses over 1,000 dogs, each individual may have to wait weeks or even months for a single opportunity to access this limited space-rendering it

		functionally ineffective in promoting socialisation or improving welfare." "PBPL housed a range of animals-including dogs, monkeys, minipigs, pigs, and sheep-but all were confined exclusively to cages, with no access to open or enriched environments even when they were housed for more than three months, sometimes exceeding nine months. While some dogs and monkeys were housed in same-sex pairs, these arrangements are insufficient to support the natural social behaviours characteristic of these species." "Critically, there were no dedicated outdoor enclosures or exercise facilities for non-human primates. This deprived the monkeys of any oppo1iunity for natural movement, physical exercise, or cognitive stimulation. The lack of outdoor access and meaningful enrichment across species poses a significant risk to both the psychological welfare and behavioural health of the animals in PBPL's care." "Environmental enrichment across all animal housing areas was grossly inadequate. In the experimental rooms for dogs, a few plastic bones were loosely scattered in the corridors. These rigid and repetitive items lacked the novelty or functionality to effectively engage the animals. No other enrichment tools or

		activities were present. Similarly, only a few minipigs were provided with enrichment in the form of cut PVC pipe sections-simple items that failed to sustain their interest or encourage exploratory behaviour. In the monkey enclosures, circular rings were suspended as the only form of enrichment. However, these minimal features were clearly insufficient to meet the cognitive and physical needs of the primates, particularly given their confinement to small cages, either alone or in same-sex pairs." "The housing for minipigs featured polymer flooring with rectangular drainage openings, which are unsuitable for 24 X 7 housing of cloven-footed animals to stand or lie down comfortably. No meaningful environmental enrichment was provided…A few minipigs were offered minimal enrichment in the form of cut PVC pipe sections, including L-shaped bends. However, these were significantly undersized relative to the pigs' body dimensions, and the design posed a clear risk of choking or injury, as the openings were small enough that animals could potentially attempt to insert their heads. This highlights a lack of considered design and a failure to meet even the most basic behavioural and welfare needs of the animals."

		“Each sheep was individually caged without any form of environmental enrichment. The complete absence of social interaction or sensory stimulation raised significant concerns about their welfare. They were kept on polymer flooring with drainage openings, which is inappropriate for 24 X 7 housing of cloven hooves and overall physiology.” “The enclosures housing the monkeys offered little room for natural movement or social interaction. There were no dedicated outdoor enclosures or exercise facilities. The narrow metal platforms inside the cage made it difficult for the animals to sit or lie down comfortably, raising serious concerns about their physical comfort and overall welfare. The only form of enrichment observed was a single coloured ring suspended in each enclosure-an effort that proved grossly inadequate, failing to provide any meaningful cognitive stimulation or physical engagement.” “Twelve cows were housed in a makeshift cattle shed with minimal infrastructure and inadequate protection from the elements. Continuous rainfall had led to water accumulation in parts of the shed, creating damp and unsanitary conditions.”

Dishonesty		"Pigs (White Yorkshire Mixed Breeds): These animals were not initially disclosed to the inspection team, despite repeated inquiries. Their presence came to light only incidentally during a meeting, when scientists-while discussing ongoing cardioiogy-related studies such as pacemaker development-unincentionally acknowledged their use." "Contrary to the facility's initial claim that no sheep were present, seven sheep were discovered by the inspection team in the experimental section during a visit to the mixed-breed pigs. This unreported presence reflects a serious disregard for regulatory compliance and a failure to meet the basic norms prescribed by CCSEA." "CCTV footage was not made available to the CCSEA inspection team despite multiple formal .and verbal requests on the day of the visit, as well as prior intimation through an official CCSEA letter…[D]despite repeated and specific requests, the team was not shown any recordings from the corridors of the dog breeding stock areas. Staff claimed that no cameras were installed in those particular locations, leaving a critical gap in visual documentation. Similarly, when the team requested footage from the

		rehabilitation area, animal entry, and the dirty corridors of the experimental housing zones, they were again informed that no CCTV cameras had been installed in those areas either." "The inspection team is of the opinion that this lack of access to key CCTV footage, combined with the absence of camera coverage in critical areas, indicates a deliberate attempt to withhold or tamper with evidence related to potential animal welfare violations."
Acknowledgement of Likelihood of Other Problems	"The violations described above are not intended to be an all-inclusive list of problems that may exist with your facility."	"While the report highlights key gaps and deficiencies observed during the inspection, it is not intended to serve as an exhaustive documentation of all operational procedures or standard practices at PBPL."