

From B (per rule 8(a))

APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

Application to be submitted to sent either to the CPCSEA (address in form A above) or Institutional Animal Ethics Committee (IAEC)

Part A

- *1. Name and address of establishment

- *2. Registration number and date of registration

3. Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C

4. Place where the animals are presently kept (or proposed to be kept)

5. Place where the experiment is to be performed (Please provide CPCEA Reg. Number)

6. Date on which the experiment is to commence and duration of experiment

7. Type of research involved (Basic Research/Educational/Regulatory)

Signature

Name and designation of Investigator

Date:

Place:

*Applicable only for application to be submitted to CPCSEA

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Seven Hills College of Pharmacy – Tirupati
Dept: Pharmacology
CPCSEA Application - Part B

Protocol form for Research proposals to be submitted to the Committee/ Institutional Animal Ethics Committee, for New Experiments or Extensions of ongoing Experiments using animals other than Non-Human Primates.

1. Project/Dissertation/Thesis title:

2. Principal Investigator/Research Guide/ Advisor:

- a. Name :
- b. Designation :
- c. Experience :
- d. Dept/Div/Lab :
- e. Mobile number :
- f. E-Mail ID :

3. List of names of all Co-Guide/Co-investigator/individuals authorized to conduct procedures under this proposal:

Name & Designation

E-Mail ID

4. Funding Source with complete address (Please attach the proof):

5. Duration of the Project:

- a) Number of months :
- b) Date of initiation (Proposed) :
- c) Date of Completion (Proposed) :

6. Detailed Study Plan/Protocol (Not more than one page)

*Tabulated Break-Up of **Total Animals Required & Summary of Protocol** attached as annexure.*

7. Study Objectives [The Aim of study and why they are Important]

Aim

Objectives

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8. Animals Required:

A(i)	Species	Mice	Rat	Rabbit	Guinea Pig
A(ii)	Strain				
B	Age/ Weight				
C	Gender				
D	Total numbers reqd.				
E	No of days, Animals to be housed				
F	Proposed source of Animals				

*Mention NA where not applicable

9. Rationale for Animal Usage:

- a) Why is animal usage necessary for these studies?
- b) Why are the particular species selected required?
- c) Why are the estimated numbers of animals essential?
- d) Similar experiments conducted in the past. If so, the number used and results obtained in brief.
- e) If yes, why a new experiment is required?
- f) Have similar experiment (s) been made any other organization/agency? If so, their results in your knowledge.

10. Description of procedure to be used:

(List and describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiment. Furnish details of injection schedules (substances, doses, sites and volumes), blood withdrawal (Volumes and sites and all anesthetics and/or analgesics dosage and routes)

Included in the detailed protocol attached as Annexure - I

Substances :
Doses :
Sites :
Volumes :

Blood withdrawal

Volumes :
Sites :

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Choice & Dose of Anesthesia / Analgesia:

Radiation (dosage and schedules) :

11. Please provide brief descriptions of similar studies from in vitro/in vivo (from other animal models) on same/similar test component or line of research. If, enough information is available, justify the proposed reasons:

12. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures (any which cause more pain than that associated with routine injection or blood withdrawal)?

If Yes, explanation and justification:

.....

13. Will survival surgery to be done? If YES, the following to be described: No
(Attach Annexure, if required)

- a. List and description of all such surgical procedures (including methods of asepsis)
- b. Names, qualifications and experience levels of operators
- c. Description of post-operative care
- d. Justification if major survival surgery is to be performed more than once a single individual animal

14. Methods of disposal post-experimentation:

Euthanasia (Specific Method) :

Method of carcass disposal :

Rehabilitation :

15. Animal Transportation Methods if Extra-institutional Transport is envisaged:

16. Use of hazardous Agents (Use of recombinant DNA-based agents or potential human pathogens requires documented approval of the Institutional Biosafety Committee(IBC). For each category, the agents and the biosafety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified)**.

a. **Radionuclide :**

b. **Biological Agents :**

c. **Hazardous chemicals :**

d. **Recombinant DNA :**

e. **Any Other (give name):**

****If, your project involved use of any of the above, attach copy of the minutes of Institutional Biosafety committee (IBC) granting approval.**

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INVESTIGATOR'S DECLARATION :

1. I certify that I have determined that the research proposal herein is not unnecessarily duplicative of previously reported research.
2. I certify that, I am qualified and have experience in the experimentation on animal.
3. For procedures listed under item 11, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.
4. I will obtain approval from the IAEC/CPCSEA before initialing any significant changes in this study.
5. Certified that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body [institutional scientific advisory committee / Funding agency / other body (to be named)].
6. Institutional Biosafety committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).
7. I certify that I will not initiate the study unless approval from CPCSEA/IAEC is received in writing. Further I certify that I will follow the recommendations of the CPCSEA/IAEC.
8. I certify that I will ensure that the rehabilitation policies are adopted.
9. I shall maintain all the Experiment Records as per the format (Form D)

Date:

Place: Tirupati

(Mr./Ms/Dr.....)
Name & signature of Principal Investigator

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Tabulated BREAK-UP of Total Animals Required

(Group-wise / Expt-wise Division of Laboratory Animals must be mentioned)

(*Use extra pages if required)

Total Groups covered in Experiments =

Animals Required Per Group =

Total Animals required for study =

Total Laboratory Animals requirement:

S.No.	M. Pharmacy			
	I st sem	II nd sem	III rd sem	IV th sem
1				

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Brief Summary of Experiment Protocol/Design

(*Outlines Only-Use extra pages if required)

Experiment Title	
Animal Species & Strain	
Gender	
Age/Weight	
Location of Animal house	
Summary of Protocol	
References	