



**Committee for the Purpose of Control and Supervision of Experiments on Ani**  
Ministry of Fisheries, Animal Husbandry and Dairying Department of Animal Husbandry and Dairying Government of Ind

**Registration No:-** 1894/PO/Re/S/16/CPCSEA

**Date of Registration:-**08/06/2016

**Registration valid till:-** 08/06/2021

**Name of the Establishment:-**School of Pharmacy

**Address of establishment:-**ITM University, Gwalior – 474 001, Madhya Pradesh

**Purpose of Registration:-**Small animal:- Research for Education purpose

**Type of Animal House Facility:-**Small Animal Facility

**Validity of registration has expired! Renewal of registration and re-constitution of IAEC is required!**

**IAEC Members**

Tij

**Internal IAEC Members**

S.NO.	MEMBER NAME	DATE OF BIRTH	DESIGNATION	QUALIFICATION	MOBILE	EMAIL	EXPERIENCE	ORGANIZATION
1	Dr. Richa Kothari	19 Jan 1970	NA( Chairperson)	Ph.D, MSc, B.Sc	9425793557	richakothari@itmuniversity.ac.in		school of pharmacy
2	Shri. Anurag Agrawal	26 Jul 1986	Biological Scientist( Member Secretary)	M.Pharm, B.pharm	9685824456	anu2pharm@gmail.com		school of pharmacy
3	Dr. Sonia Johri		Scientist from different discipline( NA)	Ph.D, MSc	9893096353	soniajohari@itmuniversity.ac.in		School of Pharmacy
4	Smt. Trappti Pathak		Scientist from different discipline( NA)	Ph.D, MSc, BSc	8458927242	trappti.pathak@itmuniyersiy.ac.in		School of Pharmacy
5	Dr. Pradeep Sharma	03 Apr 1983	Veterinarian( NA)	MVSc, BVSc	9584934804	p5315238@gmail.com		ITM University Gwalior 474001
6	Shri. Nikhil Shrivastava		Scientist Incharge of Animal House Facility( NA)	M.PHarm, B.Pharm	9893410930	nikhil.pharma@live.com		ITM University

**CPCSEA Nominee for IAEC**

SNO	NAME OF THE NOMINEE	DESIGNATION IN IAEC	ADDRESS	ORGANIZATION TO WHICH THEY BELONG
1	Dr. Rakesh Bhargava	Main Nominee	Microbiology Division, Defence Research and Development Establishment, Jhansi Road, Gwalior-474002, Madhya Pradesh	Microbiology Division, Defence Research & Development Establishment, Jhansi road, – 474 002, Madhya Pradesh
2	Dr. Manoj Sharma	Link Nominee	16-B, P.G. Enclave, Anupam Nagar Ext. 2, Near Mahesh Nagar, City Centre, Gwalior – 474 002, Madhya Pradesh	School of Studies in Pharmaceutical Scienc Jiwaji University, Gwalior / Life Member of ND
3	Dr. Abhishek Pandey	Scientist from out side of the Institute	Near Sarbati Bai Big Temple, Bada Lohar Pura, Old Shivpuri – 473 551, Madhya Pradesh	School of Studies in Pharmaceutical Scienc Jiwaji University Member, PFA
4	Dr. Bhagat Singh Jaiswal	Socially aware Nominee	D-81 Vijaya Nagar, Near Chetakpuri, Jhansi Road Gwalior, Madhya Pradesh - 474009	School Of Studies In Pharmaceutical Scien Jiwaji University, Gwalior

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No. 25/396/2010-AWD  
Government of India  
Ministry of Fisheries, Animal Husbandry and Dairying  
Department of Animal Husbandry and Dairying  
O/o Committee for Control and Supervision of Experiments on Animals  
(CCSEA)  
\*\*\*\*\*

Delhi Milk Scheme Complex,  
Shadipur, Delhi – 110008  
Date: 21.07.2023

To,

Dr M Alagusundaram, Chairman, IAEC,  
School of Pharmacy ITM University,  
Gwalior – 474 001, Madhya Pradesh  
Email: deansop@itm university.ac.in  
Mobile: 9989530761

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics Committee (IAEC)- regarding

Sir,

The registration of Animal House Facility of your establishment with CCSEA has been **renewed for a period of five years from the date of issue of this letter.**

2. The new registration number of Animal House Facility of your establishment is **1894/PO/Re/S/16/CCSEA for Research for Education purpose on small animals.** Henceforth, the new registration number may kindly be quoted in all your future correspondence with this office.

3. The CCSEA has accepted the following members recommended by the establishment.

Name of the IAEC Members	Designation in IAEC
1) Dr M Alagusundaram	Biological Scientist, Chairperson
2) Shri. Arijit Chaudhuri	Scientist from different biological discipline, Member Secretary
3) Dr. Sonia Johri	Scientist from different biological discipline
4) Mr. Nem Kumar Jain	Scientist Incharge of Animal House Facility
5) Dr.S P Upadhyaya	Veterinarian

4. CCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

Details of Nominee(s)	Nominated as
1) Prof. Suman Jain C/o Shri Mukesh Kumar Jain, Luhadiya Bhawan, Dana Oli, Lashkar, Gwalior, Madhya Pradesh Contact No :9425116181 Email :sumanmukum@rediffmail.com	Main Nominee
2) Dr. Sunil Kumar Dhiman VMD, Defence R&D Establishment (DRDE), Jhansi Road, Gwalior, MP Contact No :09435521588 Email :sunildhiman81@gmail.com	Link Nominee

Contd....



3) Shri Deepesh Parashar IPS College of Technology & Management, Shivpuri Link Rd, Gwalior, Madhya Pradesh 474001 Contact No :7000746883 Email :parashardeepesh85@gmail.com	Scientist from outside the Institute
4) Mr. Rajesh Singh Jadon 18K, Gaytri Vihar, Jaderua road, Pinto Park, Gwalior - 474006, Madhya Pradesh Contact No :9300631006 Email :drjadon@gmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CCSEA.)

5. The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CCSEA guidelines.

6. You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CCSEA.

7. It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and Main Nominee, Scientist from outside the Institute and Socially aware nominee must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC. However, Link Nominee should be invited once in a year to update him/ her about the activities of IAEC. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

8. It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CCSEA for further approval (procedure for submission of Research Protocols is available on the website of CCSEA).

Yours Sincerely,

(Dr.S.K.Dutta)

Member Secretary (CCSEA)

Copy for necessary action to: Nominees of CCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CCSEA.

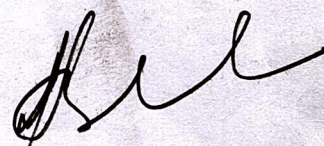


## Agenda

Date: - 23/09/2019

### THE FIFTH IAEC MEETING OF SCHOOL OF PHARMACY

1. To visit the Animal house facility in School of Pharmacy
2. Any other items with the permission of chairman



Prof. A. Balasubramaniam

Chairman, IEAC

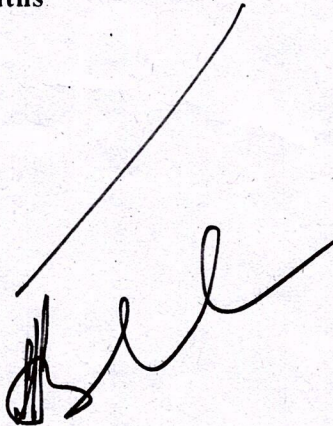


**Form C**

**Record of Animals bred / acquired: (to be maintained by the Breeder/Establishment)**

<b>Date of entry</b>	<b>No. of Animals (Specify species, sex and age)</b>	<b>No. of Animals acquired (Specify date of acquisition species, sex and age)</b>	<b>Name, Address and date &amp; from whom acquired</b>	<b>No. of animals transferred (specify date, species, sex and voucher/ (bill no. )</b>	<b>Name, address and registration No. of the Establishment to whom transferred</b>	<b>Signature</b>

No animal was acquired in last six months

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.




**Form D**

**Record of Animals Acquired and Experiments performed: (to be maintained by the Investigator)**

<b>Date of entry</b>	<b>No. of animals acquired (specify species, sex and age</b>	<b>Name, address and registration No. of the breeder from whom acquired with voucher/bill no.</b>	<b>Date and particulars of order of grant of permission by the committee</b>	<b>Date/period of experiment</b>	<b>Name and address of the person authorizing the experiment</b>	<b>Certification of the investigator authorizing the experiment that all conditions specified for such an experiment have been complied with (Signature)</b>

- Nil -

A handwritten signature in black ink, appearing to be 'S. L.', is written over a diagonal line that extends from the bottom of the table area towards the top right of the page.



## MINUTES OF THE MEETING OF THE FIFTH INSTITUTIONAL ANIMAL ETHICAL COMMITTEE OF SCHOOL OF PHARMACY- ITM UNIVERSITY- GWALIOR

1. The Fifth IAEC was conducted on 23<sup>rd</sup> September 2019 at 12 PM, in the Dean Office of PC Ray block of ITM University

2. The following members were **present** in the meeting

- |   |   |
|---|---|
| a. Dr. Rakesh Bhargava , Scientist DRDO | (Main Nominee)                            |
| b. Dr. Manoj Sharma                     | (Link Nominee)                            |
| c. Mr. Bhagat Singh Jaiswal             | (Socially aware Nominee)                  |
| d. Dr. Abhishek Pandey                  | (Scientist from outside institute)        |
| e. Dr. A. Balasubramaniam               | (Chairperson)                             |
| f. Mr. Anurag Agrawal                   | (Member Secy.)                            |
| g. Dr. Subodh Kumar Dubey               | (Scientist ICAH Facility)                 |
| h. Dr. Sonia Johari                     | (Scientist from different Bio Discipline) |
| i. Mrs. Trapti Pathak                   | (Scientist from different Bio Discipline) |
| j. Dr. Pradeep Sharma                   | (Veterinarian)                            |

3. The following member was **absent** in the meeting

- |                       |                |
|-----------------------|----------------|
| a. Dr. Pradeep Sharma | (Veterinarian) |
|-----------------------|----------------|

4. Animal house was visited and all facilities were found to be maintained. *Satisfactory.*  
Members

- |   |   |                           |
|---|---|---------------------------|
| a. Dr. Rakesh Bhargava , Scientist DRDO | (Main Nominee)                            | <i>R. Bhargava</i>        |
| b. Dr. Manoj Sharma                     | (Link Nominee)                            | <i>Manoj</i>              |
| c. Mr. Bhagat Singh Jaiswal             | (Socially aware Nominee)                  | <i>B.S. Jaiswal</i>       |
| d. Dr. Abhishek Pandey                  | (Scientist from outside institute)        | <i>Abhishek</i>           |
| e. Dr. A. Balasubramaniam               | (Chairperson)                             | <i>A. Balasubramaniam</i> |
| f. Mr. Anurag Agrawal                   | (Member Secy.)                            | <i>Anurag</i>             |
| g. Dr. Subodh Kumar Dubey               | (Scientist ICAH Facility)                 | <i>Subodh</i>             |
| h. Mrs. Trapti Pathak                   | (Scientist from different Bio Discipline) | <i>Trapti</i>             |
| i. Dr. Pradeep Sharma                   | (Veterinarian)                            | <i>Pradeep</i>            |
| j. Dr. Sonia Johari                     | (Scientist from different Bio Discipline) | <i>Sonia</i>              |

The meeting ends with a vote of thanks

*[Signature]*

Chairperson

Institutional Animal Ethical Committee,  
School of Pharmacy, ITM University, Gwalior

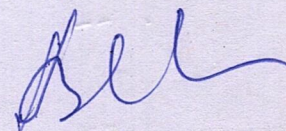


## Agenda

### THE SIXTH (6<sup>th</sup>) IAEC MEETING OF SCHOOL OF PHARMACY

Sixth IAEC meeting is proposed to be held on 19/3/2020 with following objectives

1. Confirmation of previous minutes of meeting, held on 23/09/2019
2. To get the approval for assessment of acute dermal toxicity of Emodin and plant extract and to check the Anti-psoriatic potential of Emodin and plant extract using mouse tail model of psoriasis and UV-B induced psoriasis in Wistar rats
3. Any other items with the permission of chairman



Prof. A. Balasubramaniam

Chairman, IEAC



## MINUTES OF THE MEETING OF THE SIXTH INSTITUTIONAL ANIMAL ETHICAL COMMITTEE OF SCHOOL OF PHARMACY- ITM UNIVERSITY- GWALIOR

The Sixth (VI) IAEC was conducted on 19<sup>th</sup> March 2020 at 12 PM, in the conference room of PC Ray block ITM University

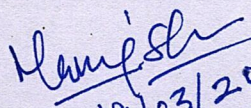
The following members were **present** in the meeting


- |  |   |
|--|---|
| a. Dr. Rakesh Bhargav , Scientist DRDO | (Main Nominee)                            |
| b. Dr. Manoj Sharma                    | (Link Nominee)                            |
| c. Dr. Bhagat Singh Jaiswal            | (Socially aware Nominee)                  |
| d. Dr. Abhishek Pandey                 | (Scientist from outside institute)        |
| e. Dr. A. Balasubramaniam              | (Chairperson)                             |
| f. Mr. Anurag Agrawal                  | (Member Secy.)                            |
| g. Dr. Subodh Kumar Dubey              | (Scientist IC A.H. Facility)              |
| h. Dr. Sonia Johari                    | (Scientist from different Bio Discipline) |
| i. Mrs. TraptiPathak                   | (Scientist from different Bio Discipline) |
| j. Dr. Pradeep Sharma                  | (Veterinarian)                            |

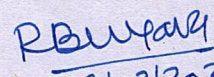
The following matters were discussed and resolved that

1. The minutes of the previous meeting which was held on 23/09/2019, was confirmed.
2. There is one proposal discussed and IAEC given approval of the project "**Assessment of Acute dermal toxicity of Emodin and plant extract and to check the Anti-psoriatic potential of Emodin and plant extract using mouse tail model of psoriasis and Ultraviolet B induced psoriasis in Rats**".
3. All IAEC members visited animal house and found satisfactory facility in the animal house.

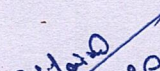
The meeting ends with a vote of thanks


  
19/03/2020

 19/03/20

  
19/03/2020



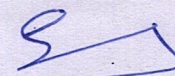
  
19/3/20

  
19/03/2020

Chairperson

Institutional Animal Ethical Committee, School of Pharmacy, ITM University, Gwalior



  
13/1/2024



## APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

Application to be submitted to the CPCSEA, New Delhi after approval of Institutional Animal Ethics Committee (IAEC)

### Part A

**1. Name and address of establishment**

School of Pharmacy, ITM University Campus, NH-44, Bypass Turari, Jhansi Road, Gwalior (M.P.) – 474001,

**2. Registration number and date of registration**

Regd. No 1894/PO/Re/S/16/CPCSEA; Dated: 8<sup>th</sup> June 2016

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

DRDE, Gwalior (MP) / CDRI, Lucknow (UP)

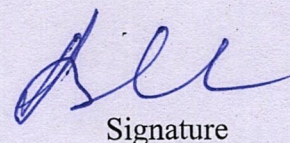
**4. Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)**

Animal House, ITM University Gwalior (1894/PO/Re/S/16/CPCSEA)

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

15/03/2020

**6. Type of research involved: Educational**



Signature

Name and Designation of Investigator

Date: 15/03/2020

Place: Gwalior

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\*The filled in Form B having above information / details / supporting documents (1 original + 14 copies and 1 soft copy in CD) should be sent to: -

The Member Secretary,

CPCSEA, Ministry of Environment & Forests, 8th floor, Jeevan Prakash Building, 25, Kasturba Gandhi Marg, New Delhi-110 001



## 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 Title:**

- A. Assessment of Acute dermal toxicity of Emodin and plant extract and to check the Anti-psoriatic potential of Emodin and plant extract using mouse tail model of psoriasis and Ultraviolet B induced psoriasis in Rats

**Principal Investigator / Research Scholar / Research Guide / Advisor:**

- |                    |                        |
|--------------------|------------------------|
| a. Name-           | Dr. A. Balasubramaniam |
| b. Designation-    | Principal/ Professor   |
| c. Dept / Div/ Lab | Pharmaceutics          |
| d. Telephone No.   | 9009790257             |
| e. Experience      | 26 Years               |

**2. List of names of all individuals authorized to conduct procedures under this proposal.**

Name & Designation	E-mail ID
Anurag Agrawal	anuragagrawal86@hotmail.com

**4. Funding source with complete address (Please attach the proof)**  
Not Available

**5. Duration of the project**

- a. Number of months : 06 Months  
b. Date of initiation (Proposed) : April 2020  
c. Date of completion (Proposed) : September 2020

**6. Detailed study plan may be given (Not more than one page)**

Tabulated Break –Up of Total Animals require & Summary of Protocol attached as Annexure – 1, 2

**7. Animals required**

- a. Species / Common name : Rat and Mice (Wistar and Albino Respectively)  
b. Age/ weight/ size : 25-30gm (Mice) 200-250 gm (Rat)  
c. Gender : Male (Rat and Mice)  
d. Number to be used : 54 Rats and 42 Mice  
e. Number of days each animal will be housed: 06 Months  
f. Proposed source of animals. : DRDE Gwalior



## **8. Rationale for animal usage**

### **a. Why is animal usage necessary for these studies?**

To determine the toxicity of any chemicals on animal skin, OECD guideline 402 has been proposed for acute dermal toxicity. Therefore by evaluating LD50, effective dose for examining anti-psoriatic effect of Emodin can be established.

### **b. Why are the particular species selected required?**

These species can easily be sensitized by exposures in the given animal models and are easily available also.

### **c. Why is the estimated number of animals essential?**

As per the protocols prescribed by OECD and noteworthy publications in the reputed journals, mentioned numbers of animals are required to check the objectives of the studies.

**Are similar experiments conducted in the past? If so, the number of animals used and results obtained in brief.**

Yes, (References 1, 2, and 3 are attached).

### **d. If yes, why new experiment is required?**

The antipsoriatic potential of Emodin has never been reported.

### **e. Have similar experiments been made by any other organization agency? If so, their results in your knowledge.**

Experiments Might be carried out on different chemicals and herbals

### **Description the procedures to be used.**

The acute dermal toxicity test (LD50) of cream containing Emodin will be determined according to the OECD guidelines no. 402 (Organization for Economic Corporation and Development) Adult wistar rats (approx.250-300 g) of either sex were used. Approximately 24 hrs prior the test, fur should be removed from the dorsal area of the trunk of the test animals by clipping or shaving. Not less than 10 % of the body surface area should be clear for the application of the test substance. Starting dose of 2,000 mg/kg (topically) of cream was given to three groups (n = 6) each. Cream should be held in contact with the skin with a porous gauze dressing and non-irritating aloe throughout a 24 hour exposure period. The treated animals were monitored for 14 days for changes in fur, eyes, behavior and toxic reactions. If the cream is safe up to the dose of 2,000 mg/kg and from results suitable dose will be chosen for each activity in each cream for further experimentation.

### **Anti-psoriatic activity (Mouse tail model)**

Select Male albino mice (n = 6) weighing 25-27 g and divided into five groups. The tails are treated locally with test creams applied to the proximal part of the tail. For the contact time of 2 h a plastic cylinder is slipped over the tail and fixed with adhesive tape. At the end of contact time the cylinders are removed and the



tails washed. Animals are treated once daily, 5 times a week, for 2 weeks. Two hours after the last treatment the animals are sacrificed and the tails prepared histologically (fixation in 4% formalin, paraplastic embedding). Longitudinal sections of about 5  $\mu$ m thickness are prepared and stained with hematoxylin-eosin.

#### **Anti-psoriatic activity (UV-B Induced Psoriasis)**

Wistar rats (male, 300 g) were selected and divided into seven groups. Hair on the dorsal skin was carefully shaved. Test creams were applied topically on the dorsal part of the skin exposed to radiation. An area (1.5–2.5 cm) on one side of the flank is irradiated for 15 min (1.5 J/cm<sup>2</sup>) at a vertical distance of 20 cm with UV-B lamps. A biphasic erythema is observed. The second phase of erythema starts 6 h after the irradiation and gradually increases, peaking between 24 and 48 h. The color is brownish-red, and the reaction is confined to the exposed area with sharp boundary. By 48–72 h after irradiation, dark-brown scale is formed on the erythematous lesion. The irradiated rats are sacrificed after various time intervals by decapitation under ether anesthesia. Skin biopsies are taken immediately, fixed in 10% formalin, and embedded in paraffin. Tissue sections (4  $\mu$ m thick) are stained with hematoxylin and eosin.

**List and describe all invasive and potentially stress full non-invasive procedures that animals will be subjected to in the course of the experiments.**

#### **Furnish details of injections/ Topical schedule**

**Substances : Emodin**

**Doses : 2000mg/kg (for acute dermal toxicity)**  
250mg/kg, 500mg/kg (for anti psoriatic activity) in each model

**Sites : Dermal Application**

**Volumes :**

**Blood withdrawal: Not Applicable**

**Volumes :**

**Sites :**

**Radiation (dosage and schedules):**

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

**NO**

11. **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.** **No**

12. **Will survival surgery be done?** **Not Applicable**  
**If Yes, the following to be described.**

**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 in major survival surgery is to be performed more than once on single individual animals.

**13. Methods of disposal post-experimentation**

a. Euthanasia (Specific method): Ketamine Induced anaesthesia

b. Method of carcass disposal : by incineration method at the animal house facility at School of pharmacy ITM University Gwalior

c. Rehabilitation :

**14. Animal transportation methods if extra-institutional transport is envisaged.**

Air conditioned vehicle

**15. 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) Radionuclides

(b) Microorganisms / Biological infectious Agents

(c) Hazardous chemicals or drugs

NA

(d) Recombinant DNA

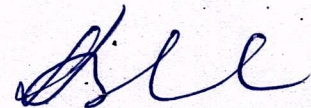
(e) Any other (give name)

If, your project involved use of any of the above, attach copy of the minutes of IBC granting approval.



### 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 animals.
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 initiating 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 shall maintain all the records as per format (**Form D**)
8. I certify that, I will not initiate the study unless approval from **CPCSEA** received in writing. Further, I certify that I will follow the recommendations of **CPCSEA**.
9. I certify that I will ensure the rehabilitation policies are adopted.



Signature

Date:

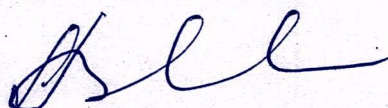


**Certificate**

**This is certify that the project titles have been approved by the IAEC.**

- A. Assessment of Acute dermal toxicity of Emodin and to check the Anti-psoriatic potential of Emodin using mouse tail model of psoriasis and Ultraviolet B induced psoriasis in Rats

Name of Chairman/ Member Secretary IAEC:

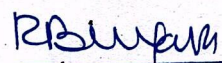


**Signature with date**

Name of CPCSEA nominee:

Dr Rakesh Bhargava

**Chairman/ Member Secretary of IAEC:**

  
19/03/2020  
**CPCSEA nominee:**

**CPCSEA nominee:**

- a. Dr. RakeshBhargav, Scientist DRDO (Main Nominee)
- b. Dr. Manoj Sharma (Link Nominee)
- c. Dr. Bhagat Singh Jaiswal (Socially aware nominee)
- d. Dr. AbhishekPandey ( Scientist from outside institute)

**(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)**



**Annexure -1**  
**Tabulated Break –UP of Total Animals Required**

**(Acute dermal toxicity)**

**For Emodin and Plant Extract**

S.No	Groups	No. of Rats/Group
1	1	06
2	2	06

**Total Groups covered in Experiment:2**

**Animals required per group: 6**

**Total Animals Required for STUDY: 12**

**Annexure -2**  
**Tabulated Break –UP of Total Animals Required**

**(Mouse tail model of Psoriasis)**

**For Herbal Compound**

S.No	Groups	No. of Mice/Group
1	Control (Negative)	06
2	Control (Positive, Standard)	06
3	Emodin-250 mg	06
4	Emodin -500 mg	06
5	Plant Extract-500 mg	06
6	Plant Extract-1000 mg	06
7	Cream base (Vehicle control)	06

**Total Groups covered in Experiments: 7**

**Animals required per group: 6**

**Total Animals Required for STUDY: 42**



**(UV-B induced Psoriasis in Rats)**

**For Herbal Compounds**

S.No	Groups	No. of Rats/Group
1	Control (Negative)	06
2	Control (Positive, Standard)	06
3	Emodin-250 mg/kg	06
4	Emodin -500 mg/kg	06
5	Plant Extract-500 mg/kg	06
6	Plant Extract-1000 mg/kg	06
7	Cream base (Vehicle control)	06

**Total Groups covered in Experiments: 7**

**Animals required per group: 6**

**Total Animals Required for STUDY: 42**

**Total Laboratory Animal requirement: 96 (42 mice for Mouse tail model, 42 Wistar rats for UV-B induced psoriasis, 12 Wistar rats for acute dermal toxicity)**

**References**

1. OECD. Test No. 402: Acute Dermal Toxicity, OECD guidelines for testing of chemicals, Section 4; OECD Publishing: France, 1987.
2. Singhal and Kansara, Cassia tora L. Creams Inhibit Psoriasis in Mouse Tail Model. Pharmaceutical Crops, 2012, 3, 1-6
3. Singhal and Kansara, Cassia tora Linn Cream Inhibits Ultraviolet-B-Induced Psoriasis in Rats. ISRN Dermatology, Volume 2012, 6 pages, doi:10.5402/2012/346510



**Record of Animals Acquired and Experiments performed: (to be maintained by the Investigator)**

<b>Date of entry</b>	<b>No. of animals acquired (specify species, sex and age)</b>	<b>Name, address and registration No. of the breeder from whom acquired with voucher/bill no.</b>	<b>Date and particulars of order of grant of permission by the committee</b>	<b>Date/period of experiment</b>	<b>Name and address of the person authorizing the experiment</b>	<b>Certification of the investigator authorizing the experiment that all conditions specified for such an experiment have been complied</b>
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**Signature**



**Record of Animals bred / acquired: (to be maintained by the Breeder/Establishment)**

<b>Date of entry</b>	<b>No. of Animals (Specify species, sex and age)</b>	<b>No. of Animals acquired (Specify date of acquisition on species, sex age)</b>	<b>Name, Address and date &amp; from who m acquired</b>	<b>No. of animals transferred (specify date, species, sex and voucher/bil</b>	<b>Name, address and registration No. of the Establishment to whom transferred</b>	<b>Signature</b>
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**FORM- E Record of  
animals sold**

(to be maintained by the establishment)\*

Date	Species & number of animals sold	Name, address and Registration Number of the establishment to whom animals sold	Date & IAEC No. of the protocols against which animals sold
	Not Applicable	Not Applicable	Not Applicable

[\* This record is required to be forwarded to O/c CPCSEA on quarterly basis. (1<sup>st</sup> April onwards)]

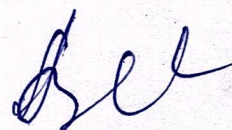


## Agenda

### THE SEVENTH (VII) IAEC MEETING OF SCHOOL OF PHARMACY

**Seventh IAEC meeting is proposed to be held on 30/12/2020 with following objectives**

1. Confirmation of previous minutes of meeting, held on 19/03/2020
2. Action taken report will be discussed
3. Any other matter with the permission of chairman



Prof. A. Balasubramaniam

Chairman, IEAC



**MINUTES OF THE MEETING OF THE SEVENTH INSTITUTIONAL ANIMAL ETHICAL  
COMMITTEE OF SCHOOL OF PHARMACY- ITM UNIVERSITY- GWALIOR**

The Seventh IAEC was conducted on 30th December 2020 at 11 AM, in the conference room of PC Ray block ITM University

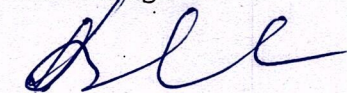
The following members were present in the meeting

- |  |   |
|--|---|
| a. Dr. Rakesh Bhargav , Scientist DRDO | (Main Nominee)                            |
| b. Dr. Manoj Sharma                    | (Link Nominee)                            |
| c. Dr. Bhagat Singh Jaiswal            | (Socially aware Nominee)                  |
| d. Dr. Abhishek Pandey                 | (Scientist from outside institute)        |
| e. Dr. A. Balasubramaniam              | (Chairperson)                             |
| f. Mr. Anurag Agrawal                  | (Member Secy.)                            |
| g. Dr. Subodh Kumar Dubey              | (Scientist IC A.H. Facility)              |
| h. Dr. Sonia Johari                    | (Scientist from different Bio Discipline) |
| i. Mrs. Trapti Pathak                  | (Scientist from different Bio Discipline) |
| j. Dr. Pradeep Sharma                  | (Veterinarian)                            |

The following matters were discussed and resolved that




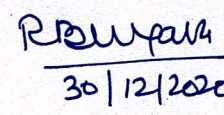

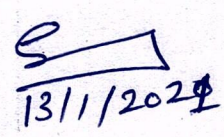

1. The minutes of the previous meeting which was held on 19/03/2020 <sup>were</sup> ~~23/09/2019~~ was confirmed.
2. Action taken report was discussed and found satisfactory use of animals in the Institute.
3. All IAEC members visited animal house and found satisfactory facility in the animal house.

The meeting ends with a vote of thanks



Chairperson

Institutional Animal Ethical Committee, School of Pharmacy, ITM University, Gwalior

     
    
13/1/2021

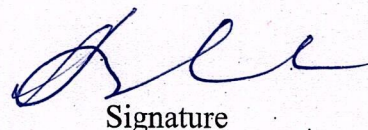


## APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

Application to be submitted to the CPCSEA, New Delhi after approval of Institutional Animal Ethics Committee (IAEC)

### Part A

1. **Name and address of establishment**  
School of Pharmacy, ITM University Campus, NH-44, Bypass Turari, Jhansi Road, Gwalior (M.P.) – 474001,
2. **Registration number and date of registration**  
Regd. No 1894/PO/Re/S/16/CPCSEA; Dated: 8<sup>th</sup> June 2016
3. **Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C**  
DRDE, Gwalior (MP) / CDRI, Lucknow (UP)
4. **Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)**  
Animal House, ITM University Gwalior (1894/PO/Re/S/16/CPCSEA)
5. **Date on which the experiment is to commence and duration of experiment.**  
[Redacted]
6. **Type of research involved: Educational**



Signature

Name and Designation of Investigator

Date: 28/12/2020

Place: Gwalior

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\*The filled in Form B having above information / details / supporting documents (1 original + 14 copies and 1 soft copy in CD) should be sent to: -

The Member Secretary,

CPCSEA, Ministry of Environment & Forests, 8th floor, Jeevan Prakash Building, 25, Kasturba Gandhi Marg, New Delhi-110 001



## **PART B**

**Protocol from 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 Title:**

NIL

**Principal Investigator / Research Scholar / Research Guide / Advisor:**

NIL

**2. List of names of all individuals authorized to conduct procedures under this proposal.**

**Name & Designation**

**E-mail ID**

**4. Funding source with complete address (Please attach the proof)**

Not Available

**5. Duration of the project**

**a. Number of months :**

**b. Date of initiation (Proposed) :**

**c. Date of completion (Proposed) :**

**6. Detailed study plan may be given (Not more than one page)**

Tabulated Break –Up of Total Animals require & Summary of Protocol attached as Annexure – 1, 2

**7. Animals required**

NIL

**7. Rationale for animal usage**

**a. Why is animal usage necessary for these studies?**

**b. Why are the particular species selected required?**

**c. Why is the estimated number of animals essential?**

**Are similar experiments conducted in the past? If so, the number of animals used and results obtained in brief.**

**d. If yes, why new experiment is required?**

**e. Have similar experiments been made by any other organization agency?**

**If so, their results in your knowledge.**

**Description the procedures to be used.**



**Anti-psoriatic activity (Mouse tail model)**

**Anti-psoriatic activity (UV-B Induced Psoriasis)**

**List and describe all invasive and potentially stress full non-invasive procedures that animals will be subjected to in the course of the experiments.**

**Furnish details of injections/ Topical schedule**

**Substances :**

**Doses :**

**Sites :**

**Volumes :**

**Blood withdrawal:**

**Volumes :**

**Sites :**

**Radiation (dosage and schedules):**

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

NO

11. 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.

No

12. Will survival surgery be done?  
If Yes, the following to be described.

Not Applicable

- 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 in major survival surgery is to be performed more than once on single individual animals.

13. Methods of disposal post-experimentation

- a. Euthanasia (Specific method):
- b. Method of carcass disposal :
- c. Rehabilitation :

14. Animal transportation methods if extra-institutional transport is envisaged.





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"CELEBRATING DREAMS"

## SCHOOL OF PHARMACY

Agenda for the 8<sup>th</sup> Institutional Animal Ethics Committee (IAEC) Meeting at School of Pharmacy, ITM University Gwalior, Madhya Pradesh on 12/08/2023 at 09.30 A.M

ITEM No.	ITEM
I	Welcome Address and Introduction of CCSEA nominated members by the Dean School of Pharmacy
II	To consider and confirm the minutes of the 6 <sup>th</sup> meeting of the IAEC held on 19 <sup>th</sup> March, 2020
III	To discuss and review the ATR
IV	To invite the submission of research protocols (Form B) and approval of application for permission for animal experiments
V	Any other matter (with the permission of Chairman, Main Nominee)

A handwritten signature in black ink, appearing to be "M. Alagusundaram".

DEAN  
M. Alagusundaram



### **MINUTES OF (VIII) IAEC MEETING**

(Minutes of IAEC meeting should be uploaded on the website of CPCSEA within 15 days after conducting the meeting)

**Name and address of establishment:** School of Pharmacy, ITM University, Gwalior-474001, Madhya Pradesh

**Registration number of establishment:** 1894/PO/Re/S/16/CCSEA

**Date and Time of the IAEC Meeting:** 12/08/2023, 9:30 AM

**Venue:** School of Pharmacy Dean's Office, PC Ray Block.

#### **Minutes of the Meeting:**

##### **Item No. 1: Welcome Address and Introduction of CCSEA nominated members by the Dean School of Pharmacy**

The Chairman and Main Nominee welcomed all members at the start of the meeting. The following agenda items were discussed in detail among members. Dr. M. Alagusundaram, Dean of the School of Pharmacy, announced the introduction of CCSEA-nominated members.

##### **Item No. 2: To consider and confirm the minutes of the 6<sup>th</sup> meeting of the IAEC held on 19<sup>th</sup> March 2020**

The minutes of the sixth meeting of the IAEC held on 6<sup>th</sup> March 2020 were read and confirmed by all the members.

##### **Item No. 3: To discuss and review the ATR (Action Taken Report)**

The committee reframed and applied for CCSEA renewal, and the inspection took place on 12.07.2023.

##### **Item No. 4: To invite the submission of research protocols (Form B) and approval of the application for permission for animal experiments**

Total 10 applications were received for approval of the protocol of the experiments on animals (Annexure - I).



**Annexure –I Decision/ Recommendation of IAEC on New Research Protocols:**

S. No.	Protocol	Protocol no.	Species proposed	Total Housing capacity for Species proposed	Number of animals proposed	Number of animals recommended by IAEC	Approved/Rejected / Deferred/ Any other remark/ observation of IAEC
1.	Design, development and evaluation of self-assembled nanotransethosomal gel loaded bioactive phytoconstituents for the treatment of autoimmune arthritis	SOP/IAEC/ 23/01	Wister Albino Rats	500	15 Male Wister Albino Rats	12	Approved
2.	Preparation and evaluation of polyherbal formulation of antihyperlipidemic, antioxidant activity and its comparative study with a marketed product	SOP/IAEC/ 23/02	Wister Albino	500	24 Male Wister Albino Rats	24	Approved
3.	Design optimization of formulation and characterization of Igaratimod nanopharmaceuticals with nutraceutical supplement for the treatment of Rheumatoid arthritis	SOP/IAEC/ 23/03	Swiss albino mice	300	12 Swiss albino mice	12	Approved
4.	Preparation, phytochemical screening, and pharmacological evaluation of polyherbal formulation containing different medicinal plants	SOP/IAEC/ 23/04	Sprague dawley	500	62 Sprague dawley rats	25	Approved



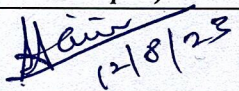
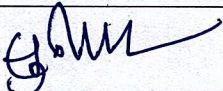
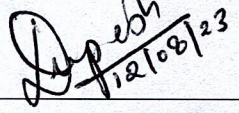

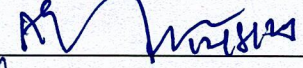
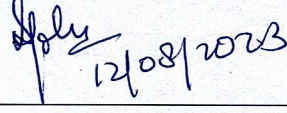
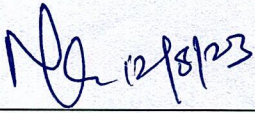
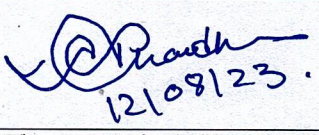
5.	Development of polyherbal formulation with medicinal plants, standardization and evaluation of its pharmacological activity	SOP/IAEC/ 23/05	Sprague dawley rats	500	62 Sprague dawley rats	25	Approved
6.	Development and evaluation of polyherbal formulations for anti-diabetic and hepatoprotective activity	SOP/IAEC/ 23/06	Wistar albino	500	42 male Wistar albino rats	25	Approved
7.	Self-assembled ultra-deformable phospholipids vesicles containing Repaglinide for the treatment of type-II diabetes	SOP/IAEC/ 23/07	Sprague dawley	500	18 Sprague dawley rats	18	Approved
8.	Design and characterization of Anti-acne phytosomal formulations of Moringa oliefera powder	SOP/IAEC/ 23/08	Sprague dawley rats and Lepus europaeus Rabbits	500 and 10 respectively	06 Sprague dawley rats and 03 Lepus europaeus Rabbits	06 Rats 03 Rabbits	Approved
9.	Elucidation of Hepatoprotective and Nephroprotective Effects of Phyto- extract in Anticancer drug induced toxicity using Rodent model.	SOP/IAEC/ 23/09	Sprague dawley	500	132 Sprague dawley rats	36	Approved
10	Preparation of polysaccharide-iron complex from piper betel and triticum aestivum and its evaluation against anemia	SOP/IAEC/ 23/10	Sprague dawley	500	25 female Wistar albino rats	25	Approved



**Item No. 5: Any other matter (with the permission of the Chairman, Main Nominee)**

After the completion of the meeting, all IAEC members visited the animal house to check the facility available.

**Attendance Sheet of the IAEC Members present in the meeting:**

S. No.	Name	Designation in IAEC	Signature with Date (The Minutes should be signed with ink. Scanned signature and date shall not be accepted.)
1	Prof. Suman Jain	Main Nominee	 12/8/23
2	Dr. Sunil Kumar Dhiman	Link Nominee	
3	Shri Deepesh Parashar	Scientist from outside of the Institute	 12/08/23
4	Mr. Rajesh Singh Jadon	Socially Aware Nominee	 12/8/23
5	Dr. M Alagusundaram	Biological Scientist, Chairperson	 12/8/23
6	Dr. Sonia Johri	Scientist form different biological discipline	 12/08/2023
7	Mr. Nem Kumar Jain	Scientist In-charge of Animal house Facility.	 12/8/23
8	Shri. Arijit Chaudhuri	Scientist In-charge of Animal house Facility, Member Secretary	 12/08/23.

All the decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and Main Nominee, Scientist from outside the Institute and Socially Aware Nominee must be present in meetings. Link Nominee can attend in case Main Nominee conveys his unavailability in writing to the chairman IAEC. However, the Link Nominee should be invited once a year to update him/her about the activities of the IAEC. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.