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Approved by Tamilnadu Government & Pharmacy Council of India, New Delhi.
Affiliated to the Tamilnadu Dr. M.G.R. Medical University,
and The Directorate of Medical Education, Chennai.

REF.NO:SSIP/ REQ/2021/005

Date: 24/11/2021

From

Department of Pharmaceutics,

SS institute of pharmacy,

Sankari, Salem (DIST) - 637301.

To

The principal,

SS institute of pharmacy,

Sankari, Salem (DIST) – 637301.

Subject: Letter for requesting permission to conduct **ADD ON COURSE** -Reg.

Respected sir,

We are requesting you to grand permission to conduct add-on course in the seminar hall on **06/12/2021 to 15/12/2021**. We wish to conduct add on course on the title "**Nanomedicine Regulatory Aspects".** This add-on course program would be a great opportunity for students to learn and that would help to shape the students.

Thanking you,

Yours truly,

PRINCIPAL,
SS INSTITUTE OF PHARMACY,
KUPPANUR (PO), SANKARI (TK),
SALEM - 637301

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JOTHIMANIVANNAN CHENNAKESAVALU
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DATE: 24/11/2021

CIRCULAR

This is to inform that will B.PHARM students have the schedule of following value - added course to be conducted by our SS Institute of Pharmacy and it as mentioned below.

COURSE NAME	SCHEDULE	DURATION	VENUE	RESOURCE PERSON
NANOMEDICINE REGULATORY ASPECTS	06/12/2021 to 15/12/2021	40 HOURS	SEMINAR HALL	M.GOMATHI

All the above-mentioned students must enroll and actively participate in the course without fail.

Note: Certificates will be issued for the eligible students after completion of the course and examination.

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SS INSTITUTE OF PHARMACY

DEPARTMENT OF PHARMACEUTICS

VENUE: SSIP Seminar hall
DATE :06/12/2021 TO 15/12/2021
TIME :10:00am-01:00pm

COURSE TITLES

NANOMEDICINE REGULATORY ASPECTS

RESOURSE PERSON

M.GOMATHI M.Pharm,
AssitantProfessor
SS Institute of pharmacy.

TOPICS

Regulatory Definitions and Frameworks

Preclinical and Clinical Evaluation

Ethical and Legal Issues

Education and Training

CONTACT

MOBILE NUMBER:
7598238661

EMAIL ADDRESS:
ssip1718@gmail.com

WEBSITE:
www.ssip.edu.in

ADDRESS

NH 47, Kuppanur Post,
Salem – Coimbatore High Way,
Manjakalpatti,
Sankari Taluk,
Salem District, Tamil Nadu – 637 301.

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SYLLABUS

NANOMEDICINE REGULATORY ASPECTS

Sl. No.	Topic	DATE
1	**Regulatory Frameworks** - Global Regulatory Frameworks for Nanomedicine - FDA Regulations for Nanomedicine in the US - EMA Guidelines for Nanomedicine in Europe	**6/12/2021-7/12/2021**
2	**Safety and Assessment** - Toxicology and Safety Assessment of Nanomedicines - Pharmacokinetics and Pharmacodynamics of Nanomedicines	**8/12/2021**
3	**Clinical and Trial Design** - Clinical Trial Design for Nanomedicines - Post-Market Surveillance and Adverse Event Reporting for Nanomedicines	**9/12/2021-13/12/2021**
4	**Intellectual Property and Quality** - Intellectual Property and Patent Issues in Nanomedicine - Nanomedicine Manufacturing and Quality Control	**14/12/2021**
5	**Labelling and Disclosure** - labelling and Disclosure Requirements for Nanomedicines	**15/12/2021**

RESOURCE PERSON:M.Gomathi

TOTAL HOURS:40Hrs

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ADD ON / CERTIFICATE VALUE ADDED COURSES ACADEMIC YEAR 2021-2022

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ACADAMIC YEAR 2021-2022

S.NO	NAME OF ADD ON CERTIFICATES PROGRAMS	COURSE CODE	NO OF STUDENT ENROLLED	TYPE OF ADD ON CERTIFICATE PROGRAMS
1.	Introduction to health apps	21IHA01	78	Self-framed course
2.	Introduction to human-Computer interactions	21IHCI02	55	Self-framed course
3.	Advanced methods in polymer techniques	21AMPT03	58	Self-framed course
4.	Neuroscience of decision making	21NDM04	60	Self-framed course
5.	Nanomedicine regulatory aspects	21NRA05	53	Self-framed course
6.	Natural gas engineering	22NGE06	56	Self-framed course
7.	AI in healthcare opportunities and challenges	22AHOC07	59	Self-framed course
8.	Advanced aquaculture technology methodology	22AATM08	117	Self-framed course

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ADD ON COURSE – ENROLLMENT LIST

NAME OF ADD ON COURSE : NANOMEDICINE REGULATORY ASPECTS

COURSE INSTRUCTORS : GOMATHI.M

YEAR OFFERED : 3rd AND 5th. SEM B.Pharm

COURSE DURATION : 40 hrs

S.NO	NAME OF THE STUDENT	REGISTER NO	COURSE
1.	VINITHA .A	561997249	3rd B.Pharm
2.	JEYASURYA.V	560020523524	2nd B.Pharm
3.	KARTHICK .D	561997218	3rd B.Pharm
4.	ISHWARYA.S	560020523523	2nd B.Pharm
5.	ANBUSELVI.S	560020523505	2nd B.Pharm
6.	ATCHAYA.K	560020523512	2nd B.Pharm
7.	THAMIZHARASAN .N	560020523547	2nd B.Pharm
8.	SARANKUMAR .T	561997235	3rd B.Pharm
9.	ARCHANA.M	560020523508	2nd B.Pharm
10.	DHANASEKARAN .A	561997209	3rd B.Pharm
11.	PRAMESHWARAN .A	561997229	3rd B.Pharm
12.	TAMILSELVAN .R	561997244	3rd B.Pharm
13.	PRAGATHI .P	560020523532	2nd B.Pharm
14.	NISHA .P	560021523562	2nd B.Pharm
15.	AZHAGIRI .T.K	561997207	3rd B.Pharm
16.	THANGAPANDIYAMMAL.T	561997245	3rd B.Pharm
17.	CHANDURU .R	560021523561	2nd B.Pharm
18.	SRITHER .R	561997240	3rd B.Pharm
19.	VETRIVEL.R	560020523566	2nd B.Pharm
20.	KAMALESH .S	561997217	3rd B.Pharm
21.	SURESH .M	561997242	3rd B.Pharm
22.	VASANTHRAJ .S	560020523552	2nd B.Pharm
23.	GULBAHAR.G	560020523521	2nd B.Pharm
24.	PAPITHA .V	560020523531	2nd B.Pharm
25.	TAMILARASAN .A	560020523546	2nd B.Pharm

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26.	DHARUN .A	561997210	3rd B.Pharm
27.	GNANAVEL.S	560020523558	2nd B.Pharm
28.	ARUN KUMAR .K	561997206	3rd B.Pharm
29.	NAGAMUGILAN.P	560020523527	2nd B.Pharm
30.	MUTHUKANNAN .S	561997224	3rd B.Pharm
31.	MUTHU.J	560020523526	2nd B.Pharm
32.	PRIYADARSHINI .V	560020523534	2nd B.Pharm
33.	THIRUMURUGAN .R	560020523549	2nd B.Pharm
34.	DEEPASREE .M	561997208	3rd B.Pharm
35.	PAVENDHIRAN .S	561997226	3rd B.Pharm
36.	SANTHOSHKUMAR .N	561997234	3rd B.Pharm
37.	ARUN .S	561997204	3rd B.Pharm
38.	SUGAVARSAN.C	560020523565	2nd B.Pharm
39.	PRADEEP .T	561997228	3rd B.Pharm
40.	GOWSALYA.V	560020523520	2nd B.Pharm
41.	SHALINI .M	561997236	3rd B.Pharm
42.	SYED YASIN S.M	560020523545	2nd B.Pharm
43.	VEERASELVAN .V	561997246	3rd B.Pharm
44.	KARTHIKEYAN .R	561997219	3rd B.Pharm
45.	BANU.S	560020523513	2nd B.Pharm
46.	ARTHI .A	561997203	3rd B.Pharm
47.	THILAGAVATHI .M	560020523548	2nd B.Pharm
48.	NANDHAKUMAR.S	560020523562	2nd B.Pharm
49.	SWATHY .M	560020523544	2nd B.Pharm
50.	ARAVIND.R	560020523507	2nd B.Pharm
51.	SHANMUGAM .G	561997237	3rd B.Pharm
52.	RAJALAKSHMI .N	560020523535	2nd B.Pharm
53.	SIVAPRAKASH .V	560020523540	2nd B.Pharm

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ADD ON COURSE –ATTENDANCE LIST

NAME OF ADD ON COURSE : NANOMEDICINE REGULATORY ASPECTS

COURSE INSTRUCTORS : GOMATHI.M

YEAR OFFERED : 3rd AND 5th. SEM B.Pharm

COURSE DURATION : 40 hrs

S. NO	NAME OF THE STUDENT	REGISTER NO	ATTENDANCE						
			6/12/21	7/12/21	8/12/21	9/12/21	13/12/21	14/11/21	15/11/21
1.	VINITHA .A	561997249							
2.	JEYASURYA.V	560020523524							
3.	KARTHICK .D	561997218							
4.	ISHWARYA.S	560020523523							
5.	ANBUSELVI.S	560020523505							
6.	ATCHAYA.K	560020523512							
7.	THAMIZHARASAN .N	560020523547							
8.	SARANKUMAR .T	561997235							
9.	ARCHANA.M	560020523508							
10.	DHANASEKARAN .A	561997209							
11.	PRAMESHWARAN .A	561997229							
12.	TAMILSELVAN .R	561997244							
13.	PRAGATHI .P	560020523532							
14.	NISHA .P	560021523562							
15.	AZHAGIRI .T.K	561997207							
16.	THANGAPANDIYAMMAL.T	561997245							
17.	CHANDURU .R	560021523561							

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18.	SRITHER .R	561997240							
19.	VETRIVEL.R	560020523566							
20.	KAMALESH .S	561997217				Ab -			Ab -
21.	SURESH .M	561997242							
22.	VASANTHRAJ .S	560020523552							
23.	GULBAHAR.G	560020523521							
24.	PAPITHA .V	560020523531							
25.	TAMILARASAN .A	560020523546							
26.	DHARUN .A	561997210							
27.	GNANAVEL.S	560020523558							
28.	ARUN KUMAR .K	561997206							
29.	NAGAMUGILAN.P	560020523527							
30.	MUTHUKANNAN .S	561997224							
31.	MUTHU.J	560020523526							
32.	PRIYADARSHINI .V	560020523534							
33.	THIRUMURUGAN .R	560020523549							
34.	DEEPASREE .M	561997208							
35.	PAVENDHIRAN .S	561997226							
36.	SANTHOSHKUMAR .N	561997234							
37.	ARUN .S	561997204							
38.	SUGAVARSAN.C	560020523565							
39.	PRADEEP .T	561997228							
40.	GOWSALYA.V	560020523520							
41.	SHALINI .M	561997236							
42.	SYED YASIN S.M	560020523545							
43.	VEERASELVAN .V	561997246							
44.	KARTHIKEYAN .R	561997219							
45.	BANU.S	560020523513							

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46.	ARTHI .A	561997203							
47.	THILAGAVATHI .M	560020523548							
48.	NANDHAKUMAR.S	560020523562							
49.	SWATHY .M	560020523544							
50.	ARAVIND.R	560020523507							
51.	SHANMUGAM .G	561997237							
52.	RAJALAKSHMI .N	560020523535							
53.	SIVAPRAKASH .V	560020523540							

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(14)

ADD ON COURSE	NANOMEDICINE REGULATORY ASPECTS
DEPARTMENT	PHARMACEUTICS
ACADEMIC YEAR	2021-2022
DATE	06/12/2021 to15/12/2021
VENUE	SEMINAR HALL
NAME: R. Sridhar	COURSE: V. Sem

14

ANSWER ALL THE QUESTIONS: **DATE:15/12/2021**

MULTIPLE CHOICE QUESTIONS **MARKS:15**

1. What is nanomedicine?
   a) The use of microscopic robots in medicine
   b) The application of nanotechnology for diagnosis, treatment, and monitoring of diseases
   c) The study of small-scale medical devices
   d) The practice of medicine at the cellular level

2. Which regulatory body is primarily responsible for overseeing nanomedicine in the United States?
   a) Environmental Protection Agency (EPA)
   b) Federal Communications Commission (FCC)
   c) Food and Drug Administration (FDA)
   d) National Aeronautics and Space Administration (NASA)

3. In the European Union, which regulation governs the approval of nanomedicines?
   a) Medical Devices Regulation (MDR)
   b) REACH Regulation
   c) European Medicines Agency (EMA) guidelines
   d) General Data Protection Regulation (GDPR)

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4. What is one of the key challenges in the regulation of nanomedicine?
   a) Lack of clinical trial requirements
   b) Standardization of testing methods
   c) High costs of production
   d) Easy approval processes

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5. How does the FDA categorize a product containing nanomaterials?
   a) As a separate category from drugs and medical devices
   b) Based on its intended use, like other medical products
   c) Automatically as a high-risk product
   d) As a food additive

6. Which of the following is a specific concern related to the safety of nanomedicines?
   a) High energy consumption during production
   b) Unknown long-term effects of nanomaterials in the body
   c) Excessive water usage in manufacturing
   d) Lack of effectiveness in small doses

7. What is the purpose of the European Union Observatory for Nanomaterials (EUON)?
   a) To provide funding for nanotechnology research
   b) To monitor the safety and regulatory status of nanomaterials in the EU
   c) To conduct clinical trials for nanomedicines
   d) To create commercial applications for nanotechnology

8. Which international organization has developed guidelines for the safety assessment of nanomedicines?
   a) World Health Organization (WHO)
   b) International Conference on Harmonisation (ICH)
   c) International Organization for Standardization (ISO)
   d) United Nations (UN)

9. What does the term "nano-specific risk assessment" refer to in the context of nanomedicine regulation?
   a) Assessing risks associated with nanoscale size and properties of materials
   b) Risk assessment for the use of nanomedicine in pediatric patients
   c) Financial risk assessment for nanomedicine companies
   d) Assessment of the environmental impact of nanomedicine

10. Why is there a need for post-market surveillance of nanomedicines?
   a) To ensure continuous safety and efficacy after approval
   b) To reduce the cost of production
   c) To comply with intellectual property regulations
   d) To increase market share

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11. In the U.S., how does the FDA handle the approval process for nanomedicines that are considered New Drug Applications (NDAs?
    a) They bypass the regular review process.
    b) They are subjected to the same rigorous review as any other drug.
    c) They are automatically fast-tracked.
    d) They are treated as over-the-counter drugs.

12. Which of the following is a common regulatory requirement for nanomedicines?
    a) Detailed characterization of the nanomaterials used
    b) No requirement for clinical trials
    c) Exemption from quality control measures
    d) No need for post-approval monitoring

13. What is the significance of Good Manufacturing Practice (GMP) in the context of nanomedicine?
    a) It is only relevant for large-scale pharmaceutical production.
    b) It ensures the consistent quality of nanomedicines.
    c) It is a guideline for environmental safety.
    d) It is irrelevant to nanotechnology.

14. Which of the following is a potential environmental concern associated with nanomedicine?
    a) Nanomaterial persistence in the environment
    b) Overuse of natural resources
    c) Excessive greenhouse gas emissions
    d) Depletion of the ozone layer

15. How does the FDA's "Nanotechnology Task Force" contribute to the regulation of nanomedicine?
    a) By providing funding for nanomedicine research
    b) By offering guidelines and recommendations for regulatory policies
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DEPARTMENT	PHARMACEUTICS
ACADEMIC YEAR	2021-2022
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ANSWER KEY: **DATE:15/12/2021**

MULTIPLE CHOICE QUESTIONS **MARKS:15**

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b) By offering guidelines and recommendations for regulatory policies
c) By fast-tracking the approval of nanomedicines
d) By conducting clinical trials

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ADD ON COURSE – MARK LIST

NAME OF ADD ON COURSE : NANOMEDICINE REGULATORY ASPECTS

COURSE INSTRUCTORS : GOMATHI.M

YEAR OFFERED : 3rd AND 5th. SEM B.Pharm

COURSE DURATION : 40 hrs

S.NO	NAME OF STUDENT	REGISTER NO	MARKS (15)	PERCENTAGE (%)
1.	VINITHA .A	561997249	13	86%
2.	JEYASURYA.V	560020523524	12	80%
3.	KARTHICK .D	561997218	14	93%
4.	ISHWARYA.S	560020523523	15	100%
5.	ANBUSELVI.S	560020523505	12	80%
6.	ATCHAYA.K	560020523512	13	86%
7.	THAMIZHARASAN .N	560020523547	13	86%
8.	SARANKUMAR .T	561997235	14	93%
9.	ARCHANA.M	560020523508	12	80%
10.	DHANASEKARAN .A	561997209	15	100%
11.	PRAMESHWARAN .A	561997229	14	93%
12.	TAMILSELVAN .R	561997244	13	86%
13.	PRAGATHI .P	560020523532	13	86%
14.	NISHA .P	560021523562	14	93%
15.	AZHAGIRI .T.K	561997207	15	100%
16.	THANGAPANDIYAMMAL.T	561997245	14	93%
17.	CHANDURU .R	560021523561	13	86%
18.	SRITHER .R	561997240	14	93%

JOTHIMANN IVANNAN CHENNAKESAVALU
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NH-544, Kuppanur (Po), Sankari (Tk), Salem(Dt) – 637301, Tamilnadu, India
Phone : 04283 241080 | E-mail : ssip1718@gmail.com | Website : www.ssip.edu.in

19.	VETRIVEL.R	560020523566	13	86%
20.	KAMALESH .S	561997217	15	100%
21.	SURESH .M	561997242	15	100%
22.	VASANTHRAJ .S	560020523552	13	86%
23.	GULBAHAR.G	560020523521	14	93%
24.	PAPITHA .V	560020523531	14	93%
25.	TAMILARASAN .A	560020523546	14	93%
26.	DHARUN .A	561997210	13	86%
27.	GNANAVEL.S	560020523558	13	86%
28.	ARUN KUMAR .K	561997206	15	100%
29.	NAGAMUGILAN.P	560020523527	14	93%
30.	MUTHUKANNAN .S	561997224	15	100%
31.	MUTHU.J	560020523526	14	93%
32.	PRIYADARSHINI .V	560020523534	15	100%
33.	THIRUMURUGAN .R	560020523549	12	80%
34.	DEEPASREE .M	561997208	15	100%
35.	PAVENDHIRAN .S	561997226	13	86%
36.	SANTHOSHKUMAR .N	561997234	15	100%
37.	ARUN .S	561997204	13	86%
38.	SUGAVARSAN.C	560020523565	15	100%
39.	PRADEEP .T	561997228	13	86%
40.	GOWSALYA.V	560020523520	15	100%
41.	SHALINI .M	561997236	13	86%
42.	SYED YASIN S.M	560020523545	13	86%
43.	VEERASELVAN .V	561997246	13	86%
44.	KARTHIKEYAN .R	561997219	14	93%
45.	BANU.S	560020523515	12	80%
46.	ARTHI .A	561997203	13	86%

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47.	THILAGAVATHI .M	560020523548	12	80%
48.	NANDHAKUMAR.S	560020523562	14	93%
49.	SWATHY .M	560020523544	13	86%
50.	ARAVIND.R	560020523507	12	80%
51.	SHANMUGAM .G	561997237	15	100%
52.	RAJALAKSHMI .N	560020523535	14	93%
53.	SIVAPRAKASH .V	560020523540	13	86%

TOTAL NUMBER OF STUDENT : 53

TOTAL NUMBER OF PERCENTAGE : 90.8%

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ADD ON COURSE : SUMMARY REPORT

Course code and Name : 21NRA05/ Nanomedicine Regulatory Aspects

Date Of Add On Programme : 06/12/2021 to 15/12/2021

Course Duration : 40 Hours

Year Offered : 5th & 3rd Sem B.Pharm

Course Instructors : M.Gomathi.,M.Pharm.

Course Outcomes :

- Understanding Regulatory Frameworks: Knowledge of global and regional regulatory bodies, such as the FDA, EMA, and ICH, and their guidelines for nanomedicine products.
- Regulatory Requirements: Insight into the specific regulatory requirements for nanomedicines, including safety, efficacy, and quality standards.
- Nanotechnology-Specific Challenges: Awareness of unique challenges and considerations in nanomedicine regulation, such as nanoparticle characterization, stability, and biodistribution.

Course Type : Add on Course

Assessment Mode:

Total Duration : 40 Hours

Number of Participants : 53

Scheme of Exam : MCQ type, offline Mode

Date of Exam : 15/12/2021

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Course Coordinator

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VALUE ADDED COURSE

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DEPARTMENT OF PHARMACEUTICS

Certificate of Participation

S. ISHWARYA

Has appreciated for his /her participation in VALUE ADDED COURSE On
NANOMEDICINE REGULATORY ASPECTS

06/12/2021 TO 15/12/2021

COORDINATOR

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R. VETRIVEL

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06/12/2021 TO 15/12/2021

COORDINATOR

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STUDENT FEEDBACK FORM

STUDENT NAME: G. Gulbahar DATE: 15.12.2021

YEAR/COURSE: B. pharm - III sem

NAME OF THE ADD ON COURSE: Nanomedicine regulatory aspects

COURSE CODE: 21NRA05 DURATION: 40 hrs

EVALUATE HONESTLY:

Questions	Excellent	Good	Fair	Poor
How was the objectives of the training			✓	
How satisfied are you with our seminar	✓			
How would you rate the clarity and effectiveness of the presenter's delivery		✓		
Was the seminar duration appropriate		✓		
How engaging and interactive was the seminar	✓			
Usefulness of the information provided		✓		
Overall quality of session	✓			

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SIGNATURE

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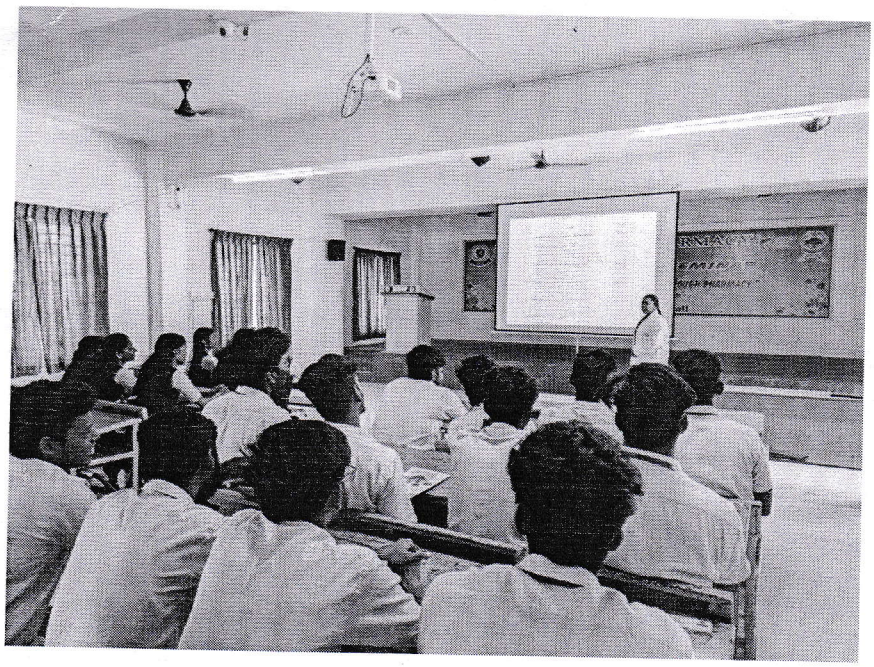
PHOTOGRAPH **DATE :** 15/11/2021

NANOMEDICINE REGULATORY ASPECTS

NAME OF ADD ON COURSE : NANOMEDICINE REGULATORY ASPECTS
COURSE INSTRUCTORS : GOMATHI.M
YEAR OFFERED : 3rd AND 5th. SEM B.PHARM
COURSE DURATION : 40 HRS



Add-on course regarding the Topic Application Nanomedicine Regulatory Aspects conducted 15/11/2021, the speech delivered By **M.Gomathi.,M.Pharm**. which was an interactive session and students could able to understand the Application of Nanomedicine Regulatory Aspects in the fields of pharmaceutical sciences

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