



# JKK MUNIRAJAH INSTITUTE OF HEALTH SCIENCES COLLEGE OF PHARMACY

(Approved by Tamil Nadu Govt. & Pharmacy Council of India - New Delhi, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai )  
Thookanaickenpalayam, Gobichettipalayam (TK), Erode (DT) - 638506, Tamil Nadu.

21.11.2022

## CIRCULAR

This is to inform all students and faculties that the Department of Pharmaceutics is Organizing a Two days workshop on **“Pharmaceutical Regulatory Affairs and Compliance”** to be held on 25/11/2022 and 26/11/2022, 10.00 AM at seminar hall.

### Resource Person:

DR. K. S. JAGANATHAN, Ph. D.,

DY. Director,

Serum Institute of India Pvt. Ltd, Pune.

&

DR. M. GNANAVEL M. Pharm, Ph. D.,

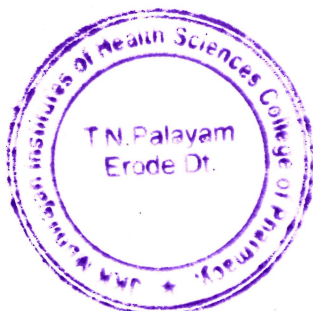
Scientist-II

Apex Laboratories Private Limited, R&D Centre, Sriperumbudur.

Interested staff and students are directed to enroll through event co-ordinator  
**Mr. K. Raja, M. Pharm.,**

Principal  
JKK Munirajah Institute of Health Sciences  
College of Pharmacy, T.N.Palayam,  
Gobi (Tk), Erode (Dt) - 638 506

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# JKK MUNIRAJAH INSTITUTE OF HEALTH SCIENCES COLLEGE OF PHARMACY



Two days seminar on

"PHARMACEUTICAL REGULATORY AFFAIRS AND  
COMPLIANCE "

Organized by Department of Pharmaceutics

DR. K. S. JAGANATHAN, PH.D,  
DY. DIRECTOR,

SERUM INSTITUTE OF INDIA PVT. LTD,  
PUNE.

DR. M. GNANAVEL M. PHARM, PH.D  
SCIENTIST-II

APEX LABORATORIES PRIVATE LIMITED,  
R&D CENTRE, SRIPERUMBUDUR.



**25 & 26 NOV 2022**  
**@ 10.00 AM**

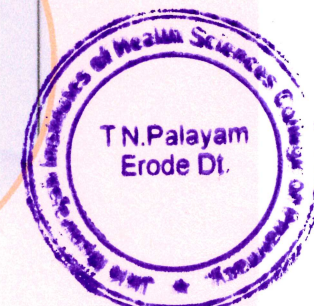
**VENUE:**  
**SEMINAR HALL,**  
**JKKMIHSCP**



*(Signature)*

Principal

JKK Munirajah Institute of Health Sciences  
College of Pharmacy, T.N.Palayam,  
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## Department of Pharmaceutics

### Two days Workshop on Pharmaceutical Regulatory Affairs and Compliance

#### RESOURCE PERSON PROFILE



**DR. K. S. JAGANATHAN, Ph. D.,**

**DY. Director,**

**Serum Institute of India Pvt. Ltd, Pune.**

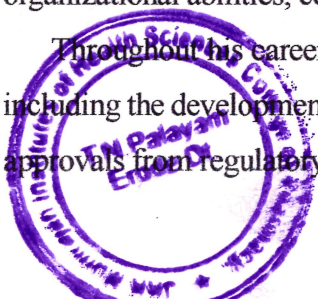
DR. K. S. Jaganathan boasts an impressive career spanning over 20 years in the Bio-Pharma Industry, encompassing R&D, Manufacturing Technology, and Commercial Production. He currently holds the position of Dy. Director, directly reporting to the Executive Management at Serum Institute of India. His professional journey includes a multitude of notable achievements:

- **Project Management and Leadership:** DR. Jaganathan has successfully managed multiple biological and vaccine projects, playing pivotal roles in developing, optimizing, scaling-up, and validating formulation processes for clinical and commercial manufacturing. His strategic planning, budgeting, and project management skills have contributed to the successful execution of New Vaccine and Life Cycle Management (LCM) vaccine projects.
- **Subject Matter Expertise:** He is recognized as a Subject Matter Expert (SME) in Biopharmaceutical formulation development and Chemistry, Manufacturing, and Controls (CMC) of Vaccine development, showcasing his proficiency in these critical areas.
- **Global Compliance and Quality:** DR. Jaganathan's expertise extends to implementing cGMP and quality systems as per WHO and FDA requirements. His leadership has been instrumental in achieving regulatory compliance, ensuring product quality, and reducing costs in a matrix organizational setup.
- **Technical Proficiency:** His comprehensive understanding of the Drug Development Process and applicable guidelines, coupled with his ability to grasp new concepts quickly, makes him a valuable asset in the field.
- **Effective Communication:** DR. Jaganathan is known for his strong analytical, problem-solving, and organizational abilities, coupled with exceptional communication skills.

Throughout his career, DR. Jaganathan has been at the forefront of numerous ground-breaking projects, including the development and scale-up of COVID-19 vaccines like Covishield and Covovax, which received approvals from regulatory bodies such as US-FDA and MHRA.

  
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He has also contributed significantly to the formulation and development of various other vaccines, such as Hexavalent, Pentavalent, Cholera, and Rotavirus vaccines, demonstrating his dedication to global healthcare.

Furthermore, his career has been adorned with prestigious honours and awards, including the Shantha Star of the Year Platinum award by Sanofi Pasteur, France, and the Bio Asia Innovation Young Scientist Award. He has excelled in his educational journey, culminating in a Ph.D. in Pharmaceutical Sciences, a post-doctoral fellowship in Japan, and numerous publications and patents to his name.

DR. K. S. Jaganathan's career is characterized by a relentless pursuit of excellence, strategic leadership, and a deep commitment to advancing the field of biopharmaceuticals and vaccines. His contributions have left an indelible mark on the industry, and he continues to inspire and lead by example in the global pharmaceutical landscape.



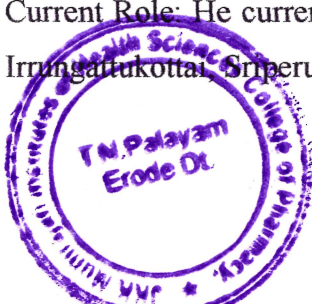
**DR. M. GNANAVEL M. Pharm, Ph. D.,**  
**Scientist-II, Apex Laboratories Private Limited,**  
**R&D Centre, Sriperumbudur.**

DR. M. Gnanavel is an accomplished professional with a strong academic background and extensive experience in the pharmaceutical industry. He holds a Doctor of Philosophy (Ph.D.) in Pharmacy, specializing in Quality Assurance, from PRIST University, Thanjavur, Tamilnadu, which he obtained in January 2015.

His commitment to academic excellence is further evident in his Master of Pharmacy (M. Pharmacy) in Quality Assurance, earned from Annamalai University, Chidambaram, Tamil Nadu, in August 2006. DR. Gnanavel's educational journey commenced with a Bachelor of Pharmacy degree from Madras Medical College, affiliated with The TN DR. MGR Medical University, Tamil Nadu, where he achieved a commendable score of 70.78% in May 2002. Additionally, he has expanded his knowledge through a Diploma in Drug Law Management from SISI, Government of India.

DR. Gnanavel's professional journey is marked by valuable contributions to the pharmaceutical sector:

- **Current Role:** He currently serves as a Scientist-II at Apex Laboratories Private Limited, R&D Centre, Irungattukottai, Sriperumbudur Taluk, Tamil Nadu, a position he has held since November 2016.



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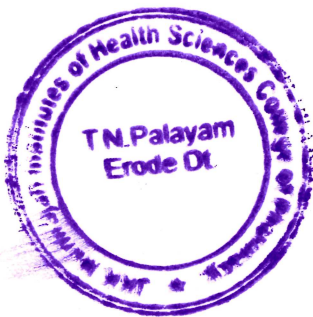
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- **Quality Assurance Expertise:** DR. Gnanavel's expertise lies in Quality Assurance, where he has taken charge of developmental activities and product transfers.
- His responsibilities include reviewing and approving process validation protocols and reports for tablets and capsules, as well as managing the Change Control Program and deviations. He plays a pivotal role in ensuring compliance with internal and external audits, including regulatory inspections.
- **Regulatory Experience:** DR. Gnanavel has actively participated in and handled numerous regulatory inspections, including those by MHRA, USFDA, WHO (Geneva), NDA (Uganda), PMPB (Malawi), TFDA (Tanzania), ANVISA (Brazil), and Indian GMP inspections.
- **Project Management:** He has a strong background in project management, having served as a coordinator for various departments, including Technology Transfer, Formulation Development, Engineering, Utility, Production (Qualification and Master Batch Records), and Packing Development. His contribution extends to coordinating with the Regulatory department for various documentation activities.
- **Leadership Roles:** DR. Gnanavel is known for his leadership capabilities, both as an effective team player and as a logical thinker with a positive attitude. He has actively contributed to internal training programs and served as an Executive Council Member of the Pondicherry Pharmacy Council from September 2013 to September 2018.

DR. M. Gnanavel's profile is a testament to his dedication to pharmaceutical quality assurance and his ability to excel in a range of roles within the industry. His strong educational foundation, coupled with his practical expertise, makes him a valuable asset in the pharmaceutical and quality assurance domains.

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## REPORT ON THE SEMINAR

**Title:** Pharmaceutical Regulatory Affairs and Compliance

**Date:** 25/11/2022 - 26/11/2022

**Resource Person:** DR. K. S. JAGANATHAN, Ph. D., & DR. M. GNANAVEL M. Pharm, Ph. D.,

**Event Coordinator:** Mr. K. Raja, M. Pharm.,

**Total Participant(s):** 113

### Description of the program:

The Pharmaceutical Regulatory Affairs and Compliance program is a pivotal educational endeavour poised to unravel the intricacies of regulatory frameworks and compliance standards within the pharmaceutical industry. Set to take place on 25/11/2022 to 26/11/2022, this program is thoughtfully designed to empower participants with the knowledge and expertise needed to navigate the complex landscape of pharmaceutical regulations. Orchestrated by adept coordinator Mr. K. Raja, M. Pharm., this program assembles a cohort of industry professionals to delve into the realm of regulatory affairs under the guidance of distinguished resource person DR. K. S. Jaganathan, Ph. D., and DR. M. Gnanavel M. Pharm, Ph.D.,

### Program Outcome:

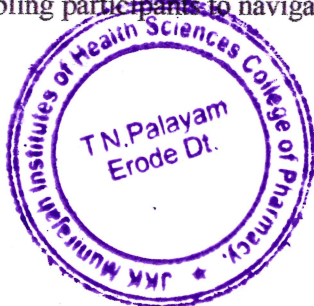
Engagement in the Pharmaceutical Regulatory Affairs and Compliance program promises participants a spectrum of invaluable outcomes, including:

**Regulatory Proficiency:** Attain a comprehensive grasp of pharmaceutical regulatory frameworks, guidelines, and protocols at local, national, and international levels, ensuring adherence to stringent regulatory requirements.

**Quality Assurance Excellence:** Acquire insights into establishing and maintaining pharmaceutical quality systems that align with regulatory standards, fostering a culture of quality and compliance within organizations.

**Product Lifecycle Management:** Develop a profound understanding of the regulatory considerations spanning the entire product lifecycle, from research and development to post-market surveillance and vigilance.

**Risk Mitigation Strategies:** Cultivate the ability to identify, assess, and mitigate regulatory risks and challenges, enabling participants to navigate potential obstacles while ensuring product safety and efficacy.



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**Global Market Access:** Explore strategies for obtaining and maintaining market approvals and certifications across international borders, facilitating the global distribution of pharmaceutical products.

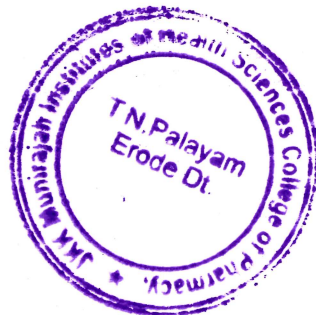
**Effective Communication Skills:** Hone communication prowess for interactions with regulatory agencies, stakeholders, and cross-functional teams, facilitating seamless compliance-related discourse and fostering productive relationships.

Coordinator Mr. K. Raja, M. Pharm., has meticulously curated the Pharmaceutical Regulatory Affairs and Compliance program to empower participants with a robust understanding of regulatory intricacies, fostering a culture of compliance and quality within the pharmaceutical landscape. The guidance of resource persons DR. K. S. Jaganathan, Ph. D., and DR. M. Gnanavel M. Pharm, Ph. D., an accomplished expert in the field, will illuminate the nuanced aspects of regulatory affairs, bridging theory with practical application through engaging discussions and real-world scenarios.

This program stands as a beacon of opportunity for participants to immerse themselves in the world of pharmaceutical regulations and compliance, equipping them to uphold the highest standards of quality, safety, and ethics while navigating the dynamic regulatory environment.

**Event Coordinator**

**Principal**  
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## Two days Workshop on Pharmaceutical Regulatory Affairs and Compliance

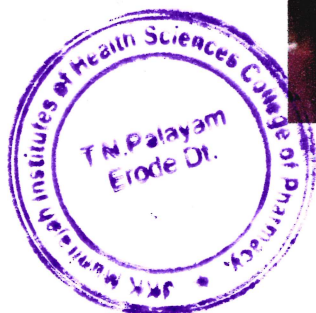
### Photos of the Programme




Two days Workshop on Pharmaceutical Regulatory Affairs  
and Compliance on 25/11/2022 at Seminar Hall.



Two days Workshop on Pharmaceutical Regulatory Affairs  
and Compliance on 25/11/2022 at Seminar Hall.



  
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## PHARMACEUTICAL REGULATORY AFFAIRS AND COMPLIANCE

### Participants List

**Resource Persons:** DR. K. S. JAGANATHAN, Ph. D.,

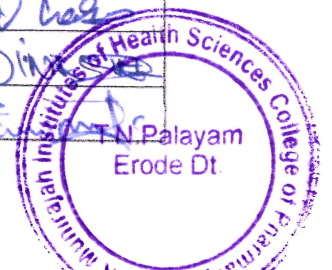
DR. M. GNANAVEL M. Pharm, Ph. D.,

**Date:** 25/11/2022 and 26/11/2022

S. No	Name of Student	Course	Registration Number	Signature
1	VIGNESHKUMAR S	LATERAL ENTRY	560022516595	Vignesh
2	ABARNA S	II BPHARM	560021516501	Abarna
3	ABINAYA S	II BPHARM	560021516502	Abinaya
4	ABISHEK R K	II BPHARM	560021516503	Abishek
5	AHAMED USMAN N	II BPHARM	560021516504	Ahmed
6	AJITHKUMAR A	II BPHARM	560021516505	Ajith
7	AMBIKA S	II BPHARM	560021516506	Ambika
8	ANANDHI G R	II BPHARM	560021516507	Anandhi
9	ANBUMANI C	II BPHARM	560021516508	Anbumani
10	ANUTHRA A	II BPHARM	560021516509	Anuthra
11	ARUN A	II BPHARM	560021516510	Arun
12	ARUNRAJ K	II BPHARM	560021516511	Arunraj
13	ARUNRAJ K	II BPHARM	560021516512	Arunraj
14	BHARATHKANNAN M	II BPHARM	560021516513	Bharath
15	CHANDRU A	II BPHARM	560021516514	Chandru
16	CHANDRU K	II BPHARM	560021516515	Chandru
17	CHINNAKANNAN K	II BPHARM	560021516516	Chinnakannan
18	DEEPASELVI T	II BPHARM	560021516517	Deepa
19	DHANASRI K	II BPHARM	560021516518	Dhanasri
20	DHANUSH S	II BPHARM	560021516519	Dhanush
21	DHARANI R S	II BPHARM	560021516520	Dharani
22	DHARUN PRAKASH M	II BPHARM	560021516521	Dharun
23	DINESH K	II BPHARM	560021516522	Dinesh
24	FARISH MOHAMED A M	II BPHARM	560021516523	Farish

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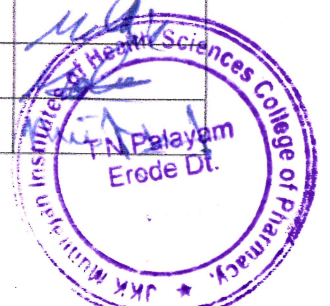
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S. No	Name of Student	Course	Registration Number	Signature
25	GOBIKA R	II BPHARM	560021516524	Gobika R
26	GOKILA K	II BPHARM	560021516525	Gokila K
27	GOKULNATH V	II BPHARM	560021516526	Gokulnath V
28	GOWRI SHANKAR V	II BPHARM	560021516527	Gowri Shankar V
29	GOWRIMALA I	II BPHARM	560021516528	Gowri Mala I
30	GOWTHAM S	II BPHARM	560021516529	Gowtham S
31	GUGAPRIYA M	II BPHARM	560021516530	Gugapriya M
32	GUNA L	II BPHARM	560021516531	Guna L
33	HARI NIVAS V	II BPHARM	560021516532	Hari Nivas V
34	HARINI K	II BPHARM	560021516533	Harini K
35	HEMALATHA V	II BPHARM	560021516534	Hemalatha V
36	HEMARANI S	II BPHARM	560021516535	Hemarani S
37	INDIRA M	II BPHARM	560021516536	Indira M
38	JAGATHEESAN M	II BPHARM	560021516537	Jagatheesan M
39	JAYAPRAKASH J	II BPHARM	560021516538	Jayaprakash J
40	JENITHA M	II BPHARM	560021516539	Jenitha M
41	JOSHUA M	II BPHARM	560021516540	Joshua M
42	KARTHICK K	II BPHARM	560021516541	Karthick K
43	KAVIMANI S A	II BPHARM	560021516543	Kavimani S A
44	KAVIN S	II BPHARM	560021516544	Kavin S
45	KAVYASHREE C S	II BPHARM	560021516545	Kavyashree C S
46	KIRUTHIKA G	II BPHARM	560021516546	Kiruthika G
47	KOKILA A	II BPHARM	560021516547	Kokila A
48	MADHESH G	II BPHARM	560021516548	Madhesh G
49	MANOJ J	II BPHARM	560021516549	Manoj J
50	MARUDHUPANDIYAN S	II BPHARM	560021516550	Marudhupandiyana S
51	MEHAVARSHINI K	II BPHARM	560021516551	Mehavarshini K
52	MELBIN J	II BPHARM	560021516552	Melbin J
53	MOHANAPRIYAN K	II BPHARM	560021516553	Mohanapriyan K
54	MOHANASUNDARAM A	II BPHARM	560021516554	Mohanasundaram A

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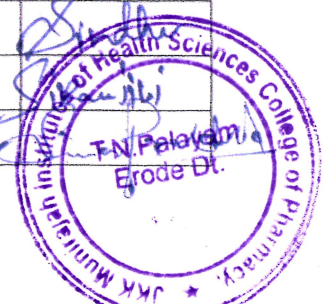
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S. No	Name of Student	Course	Registration Number	Signature
55	MOHANRAJ G	II BPHARM	560021516555	Mohanraj
56	MOHANRAM N	II BPHARM	560021516556	Mohanram
57	MOORTHY M	II BPHARM	560021516557	MOORTHI
58	MUNEESWARAN I	II BPHARM	560021516558	muneeswaran
59	NAVANEETHAKRISHNAN J	II BPHARM	560021516559	Naveenth
60	NISHA K	II BPHARM	560021516560	nisha
61	NITHISHKUMAR R	II BPHARM	560021516561	Nithish Kumar
62	NITHYA KEERTHI R	II BPHARM	560021516562	Nithya Keerthi
63	PARASURAMAN T	II BPHARM	560021516563	Parasuraman
64	PARTHIPAN M	II BPHARM	560021516564	Parthipan
65	PAVITHRA S	II BPHARM	560021516565	Pavithra
66	PRASANNA S	II BPHARM	560021516566	Prasanna
67	PRATHAP P	II BPHARM	560021516567	Prathap
68	PRITHIVIRAJ V	II BPHARM	560021516568	Prithviraj
69	RAGUL P	II BPHARM	560021516569	Ragul
70	RAJ KUMAR M	II BPHARM	560021516570	Raj Kumar
71	RAJESHKANNAN R	II BPHARM	560021516571	Rajeshkannan
72	RANJANI V	II BPHARM	560021516572	Ranjani
73	RITHIKADEVI N	II BPHARM	560021516573	Rithika Devi
74	SANJEEVI T	II BPHARM	560021516574	Sanjeevi
75	SARANYA G	II BPHARM	560021516575	Saranya
76	SARVESHWARAN S	II BPHARM	560021516576	Sarveshwaran
77	SELVARAJA V	II BPHARM	560021516578	Selvaraja
78	SELVASURYA K	II BPHARM	560021516579	Selvasurya
79	SHALINI S	II BPHARM	560021516580	Shalini
80	SHAVEETHA A	II BPHARM	560021516581	Shaveetha
81	SHIBI S R	II BPHARM	560021516582	Shibi
82	SINDHU R	II BPHARM	560021516583	Sindhu
83	SIRANJIVI D	II BPHARM	560021516584	Siranjivi
84	SIVAPRAKASH M	II BPHARM	560021516585	Sivaprakash

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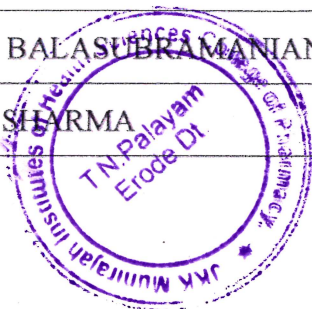




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S. No	Name of Student	Course	Registration Number	Signature
85	SNEKA K	II BPHARM	560021516586	
86	SOWMIYA SRI S	II BPHARM	560021516587	
87	SUGANTHAN M	II BPHARM	560021516588	
88	SWETHA S	II BPHARM	560021516589	
89	AMARNATH V	I MPHARM	261122516501	
90	DEEPIKA P	I MPHARM	261122516502	
91	NADIMA RASHEED K	I MPHARM	261122516503	
92	SATHISHKUMAR R	I MPHARM	261122516504	
93	SIVA BHARATHI P	I MPHARM	261122516505	
94	TAMILARASAN K	I MPHARM	261122516506	
95	THAMARAISEL VI L	I MPHARM	261122516507	
96	BHARANI T	II MPHARM	261121516501	
97	DEVI BALA N	II MPHARM	261121516502	
98	KAVIYA K	II MPHARM	261121516503	
99	LOGESH E	II MPHARM	261121516504	
100	MANIMEKALA K	II MPHARM	261121516505	
101	PRATHEEPA S	II MPHARM	261121516507	
102	PREETHI R	II MPHARM	261121516508	
103	RAJESHWARI M K	II MPHARM	261121516509	
104	VANNILA J	II MPHARM	261121516510	
105	VASUDEVAN G	II MPHARM	261121516511	
106	YATHEESH R	II MPHARM	261121516512	
107	DR. S. SELVARAJ	Associate Professor	Department of Pharmaceutics	
108	Mr. S. KANNAN	Associate Professor	Department of Pharmaceutics	
109	Mr. K. BALASUBRAMANIAN	Assistant Professor	Department of Pharmaceutics	
110	Mr. S. SHARMA	Assistant Professor	Department of Pharmaceutics	



Principal

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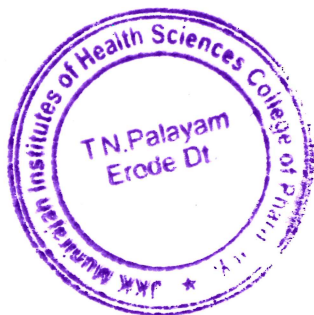


# JKK MUNIRAJAH INSTITUTE OF HEALTH SCIENCES COLLEGE OF PHARMACY

( Approved by Tamil Nadu Govt. & Pharmacy Council of India - New Delhi, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai )  
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S. No	Name of Student	Course	Registration Number	Signature
111	Mrs. D. VASUMATHI	Assistant Professor	Department of Pharmaceutics	
112	Mr. D. SUNDARARAJAN	Assistant Professor	Department of Pharmaceutics	
113	Mr. K. GOBINATH	Assistant Professor	Department of Pharmaceutics	

Event Coordinator



Principal

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