JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION'S

ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY

Approved by: Pharmacy Council of India, New Delhi &

Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.

Accredited by NAAC "A" Grade and ISO Certified

Ethirmedu, B. Komarapalayam - 638183, Namakkal Dist. Tamilnadu, India.

Website: www.jkkmmrfpharmacy.edu.in / e.mail : principal@jkkmmrfpharmacy.edu.in

Contact No : +919789456750, +919943066944, +919943069944

Dr. N. SENTHILKUMAR, Ph.D.,
Principal

DATE: 02/02/2024

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

REPORT

SEMINAR TITLE- THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING

VENUE: SEMINAR HALL **DATED: 30/01/2024**

RESOURCE PERSONS:

Mr.R.VIJAYAMIRTHARAJ.,M.PHARM,
JKKMMRFS ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
KOMARAPALAYAM

DR.P.KALAISELVI.,M.PHARM,PH.D
JKKMMRFS ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
KOMARAPALAYAM

No. of students enrolled: 350 **No. of students certified: 348**

No. of students certified in our institution:56

INTRODUCTION

Analytical chemistry plays a crucial role in the entire process of **drug development and testing**, helping ensure the quality, safety, and efficacy of new pharmaceuticals. Analytical techniques are employed at every stage of drug discovery, formulation, manufacturing, and clinical testing to assess the **chemical composition**, **purity**, **stability**, and **biological activity** of a drug. These techniques are not only essential for meeting regulatory standards but also for providing critical data that guide decision-making and optimization during the drug development lifecycle.

Programme Co-ordinator **HOD** **Principal**

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY Komarapalayam 638 183

Dr. N.SENTHILKUMAR,
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ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

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Dr. N. SENTHILKUMAR, Ph.D.,
Principal

Date: 25/01/2024

REF.NO: JKKM/PH/SEMINAR/REQ/2024/03

From

Department of Pharmaceutical Chemistry and Analysis,
JKKMMRF'S Annai JKK Sampoorani Ammal College of Pharmacy,
Komarapalayam, Namakkal [Dist],
Tamil Nadu,
PIN:638183.

To

The Principal,
JKKMMRF'S Annai JKK Sampoorani Ammal College of Pharmacy,
Komarapalayam, Namakkal [Dist]
Tamil Nadu,
PIN:638183.

Respected Sir,

Subject: **Letter for requesting Permission to conduct seminar regarding:-**

We are writing this letter to request permission to conduct a seminar in the Seminar hall on 30/01/2024. We wish to conduct the seminar on **THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING**. We believe that this will be a very informative session that many students will wish to attend.

We request you to kindly permit to conduct training program as this would be a great opportunity for Students to learn all about **THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING** that would help to shape the students.

Looking forward for your approval.

Thank you

Yours sincerely,

Signature of HOD

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
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CIRCULAR

This is to inform all the students of our college that the seminar on **THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING** for the academic year 2023-24 will be commenced on for all the batches. Hence request all the interested candidates to register for the seminar.

COURSE NAME	SCHEDULE	VENUE	RESOURCE PERSON
SEMINAR ON THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING	30/01/2024 FN (10.30 to 12 pm) (2 HOURS) & AN (2 to 4 pm) (2 HOURS)	SEMINAR HALL	Mr.R.VIJAYAMIRTHARAJ & DR.P.KALAISELVI

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

NOTE: Certificates should be issued to all the students after completion of the course and examination.

Programme Co-ordinator

HOD

Principal

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SYLLABUS

Dr. N. SENTHILKUMAR, Ph.D.,
Principal

COURSE NAME	SCHEDULE	VENUE SEMINAR HALL	RESOURCE PERSON
SEMINAR ON THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING	30/01/2024 FN (10.30 to 12 pm) (2 HOURS) & AN (2 to 4 pm) (2 HOURS)	ANALYTICAL TECHNIQUES IN DRUG DEVELOPMENT AND STABILITY TESTING	Mr.R.VIJAYAMIRTHARAJ
		FACTORS AND REGULATORY CONSIDERATIONS ABOUT DRUG DEVELOPMENTAND STABILITY TESTING	DR.P.KALAISELVI

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY Komarapalayam 638 183

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JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY, KOMARAPALAYAM

One day seminar on

THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING

Organized by

DEPARTMENT OF PHARMACEUTICAL ANALYSIS AND INTERNAL QUALITY ASSURANCE CELL(IQAC)

RESOURCE PERSONS

Mr.R.VijayAmirtharaj.,M.Pharm.,
Professor.,
Department of Pharmaceutical Chemsitry & Analaysis.,
JKKMMRF'S Annai JKK Sampoorani Ammal College of Pharmacy.Komarapalayam.

Dr.P.Kalaiselvi.,M.Pharm.,Ph.D.,
Associate Professor.,
Department of Pharmaceutical Chemsitry & Analaysis.,
JKKMMRF'S Annai JKK Sampoorani Ammal College of Pharmacy.Komarapalayam.

VENUE

SEMINAR HALL

30 JANUARY 2024

TIME : 10 TO 4 PM

Dr. N.SENTHILKUMAR,
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Dr. N. SENTHILKUMAR, Ph.D.,
Principal

ABOUT THE TOPIC

SEMINAR ON THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING INTRODUCTION

Stability testing is a crucial step in the drug development process, ensuring that a pharmaceutical product maintains its **potency**, **purity**, and **safety** throughout its shelf life. Analytical chemistry plays a central role in **stability testing**, providing the methods and techniques required to assess how a drug's physical and chemical properties change over time under various environmental conditions, such as temperature, humidity, light exposure, and storage conditions.

Importance of Stability Testing

- **Shelf Life Determination**: Stability testing helps determine the **expiration date** or **shelf life** of a drug product. This is critical for regulatory approval, as a drug must be proven to remain effective and safe for a specific duration before being marketed to the public.
- **Formulation Optimization**: Stability data guide the formulation of drugs, helping researchers optimize excipients, preservatives, and packaging materials to ensure that the drug maintains its desired characteristics over time.
- **Regulatory Compliance**: Regulatory agencies like the **FDA** and **EMA** require stability data to approve drug products. This data ensures that drugs meet stringent quality standards, remain safe throughout their shelf life, and do not degrade into harmful by-products.

Key Analytical Techniques in Stability Testing

Analytical chemistry provides a variety of methods for evaluating the stability of drug formulations and ensuring their integrity during long-term storage. Some of the most common techniques include:

1. **High-Performance Liquid Chromatography (HPLC)**:
   - HPLC is one of the most widely used techniques in stability testing to measure the **degradation products** and **impurities** that may form over time.
   - It allows the **quantification of the active pharmaceutical ingredient (API)** and the detection of any breakdown products, which is critical for determining whether the drug remains effective and safe.
2. **Mass Spectrometry (MS)**:
   - Mass spectrometry is used in combination with HPLC (LC-MS) or as a standalone technique to analyze the **molecular weight** and **structural characteristics** of degradation products.
   - It provides detailed information on **chemical stability** and helps identify unexpected degradation products or impurities.
3. **Accelerated Stability Testing**:

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- Accelerated stability testing involves subjecting the drug to **higher-than-normal temperature and humidity** conditions to simulate long-term storage in a shorter time frame.
- UV-Vis spectroscopy can be used to monitor changes in the **absorbance** of a drug over time, indicating chemical degradation or changes in its formulation.
- It is often used to assess the stability of **oral solutions**, **injectables**, and other formulations that absorb light in the UV range.

4. **Thermal Analysis (DSC, TGA)**:
   - **Differential scanning calorimetry (DSC)** and **thermogravimetric analysis (TGA)** help evaluate the **thermal stability** of the drug substance and its formulation. These techniques analyze how the drug and excipients respond to temperature changes, which can indicate potential degradation or loss of potency.
5. **Chromatographic Stability Testing**:
   - **Thin-layer chromatography (TLC)** and **gas chromatography (GC)** can also be applied to test for the presence of degradation products, although HPLC is more commonly used for its sensitivity and precision in detecting impurities.
6. **Accelerated Stability Studies for Packaging**:
   - In addition to the drug substance itself, the **packaging material** must also be evaluated for stability. Analytical chemistry techniques help ensure that the packaging doesn't affect the drug's stability or introduce impurities. For example, **leachables and extractables testing** can identify substances from packaging materials that might migrate into the drug product.

Factors Influencing Drug Stability

Several environmental and chemical factors impact the stability of pharmaceuticals, which analytical chemistry helps assess:

- **Temperature**: Drugs may degrade faster at higher temperatures. Stability testing under different temperature conditions (e.g., accelerated testing) can predict how the drug will perform over time.
- **Humidity**: The presence of moisture can promote the **hydrolysis** of certain drug formulations, especially tablets and powders. Analytical chemistry techniques help monitor the water content in drug products and determine the stability of moisture-sensitive drugs.
- **Light Exposure**: Certain drugs are sensitive to light, and exposure can lead to **photodegradation**. UV-Vis spectroscopy and other techniques help measure light-induced degradation.
- **Oxygen**: Oxidation can degrade some drug compounds. Analytical chemistry methods such as **headspace gas chromatography** are used to detect the presence of oxygen or oxidation by-products.

Regulatory Considerations

Regulatory agencies like the **FDA**, **EMA**, and **WHO** have established guidelines for stability testing, which include real-time and accelerated stability studies, testing under **ICH** (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) conditions, and **long-term storage** requirements. Analytical chemistry methods help produce data that demonstrate compliance with these standards.

1. **ICH Guidelines**:
   - The **International Council for Harmonisation** (ICH) provides stability testing guidelines that require drugs to be tested under **controlled temperature** (usually 25°C), **relative humidity** (60%), and over a **long period** (typically 12 months).
   - Analytical chemistry plays a key role in these studies by measuring the **rate of degradation**, identifying impurities, and ensuring that the drug's quality remains within acceptable limits.
2. **Real-Time Stability Studies**:
   - In contrast to accelerated studies, **real-time stability** studies are conducted over the anticipated shelf life of a drug. Analytical techniques are used to monitor the drug at various intervals to ensure it remains stable and effective throughout the period.

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Conclusion

The role of **analytical chemistry in stability testing** is indispensable in ensuring that pharmaceutical products maintain their **integrity**, **efficacy**, and **safety** throughout their shelf life. From testing the chemical stability of the active pharmaceutical ingredient to evaluating the effects of environmental factors like temperature and humidity, analytical methods help predict the **long-term performance** of a drug. This guarantees that patients receive medications that are **safe**, **effective**, and **of the highest quality**, while also fulfilling the regulatory requirements needed for drug approval and commercialization.

Programme Co-ordinator

HOD

Principal

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Principal

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

SEMINAR FEEDBACK FORM

STUDENT NAME: DATE:

YEAR/ COURSE:

NAME OF THE SEMINAR: DURATION:

EVALUATE HONESTLY:

Questions	Excellent	Good	Fair	Poor
The objectives of the training were				
The instructor's contribution to the course was:				
The presentation materials were relevant				
The instructor's effectiveness in teaching the subject matter was:				
Answers to the students questions by the instructor				
The venue was appropriate for the event				
Course organisation was:				
Level of course was				
Course content was:				

Student Participation

1. On average, how many hours a week did you spend on this course (in and out of class)?
   A)0-2 B) 2-5 C)6-10 D)11-14 E)15UP
2. What grade do you expect in this course?
   A)BELOW 50% B) 50-60% C) 60-70% D) 70-80% E) ABOVE 80%

SIGNATURE

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Principal

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

STUDENT FEEDBACK FORM

NAME OF STUDENT: **REGISTRATION NO:**
COURSE: **YEAR & SEMESTER:**
SEMINAR TOPIC: **DATE & TIME:**

1. **Overall, how satisfied were you with this seminar?**
   - Very satisfied
   - Satisfied
   - Neutral
   - Dissatisfied
   - Very dissatisfied

2. **How clear were the ideas and concepts we presented?**
   - Extremely clear
   - Very clear
   - Moderately clear
   - Not very clear
   - Not at all clear

3. **What percentage of the information was new to you?**
   - 100%
   - 75%
   - 50%
   - 25%

4. **How informative did you find our seminar?**
   - Extremely Informative
   - Very Informative
   - Moderately Informative
   - Not very informative
   - Not informative at all

5. **Were there any technical issues that prevented you from seeing or hearing the seminar?**

- Yes
- No

6. **Would you like to learn more about this topic?**

- Yes
- No

7. **Rate the content of the slides/virtual aid?**

- Extremely clear
- Very clear
- Moderately clear
- Not very clear
- Not at all clear

8. **How accurate was the session description?**

- Extremely clear
- Very clear
- Moderately clear
- Not very clear
- Not at all clear

9. **How did the session compare to your expectations?**

- Excellent
- Good
- Fair
- Poor
- Not at all clear

10. **How would you rate the content of the seminar?**

- 1
- 2
- 3
- 4
- 5

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
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Student Name with Signature

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
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Dr. N. SENTHILKUMAR, Ph.D.,
Principal

REPORT SUMMARY

DURATION OF COURSE	**4** HOURS
TOTAL PARTICIPANTS ENROLLED	**350**
SUCCESSFULLY COMPLETED	**348**
TYPE OF FEED BACK ASSESSMENT	**Multiple choice questions(MCQ'S)**
COURSE OUTCOME	Identify various analytical techniques used in drug testing and their significance in ensuring drug Safety and efficacy. Demonstrate knowledge of common analytical methods (e.g., chromatography, spectrophotometry, mass spectrometry) used for drug analysis. Apply these methods to test the quality, stability, and purity of pharmaceutical products. Understand the significance of Good Manufacturing Practice (GMP) and how analytical chemistry supports quality assurance in drug manufacturing. Conduct stability studies and evaluate the shelf-life of drug products. Gain knowledge of emerging and advanced analytical techniques in pharmaceutical testing (e.g., high-resolution mass spectrometry, proteomics, and metabolomics).Assess the potential of these techniques in improving drug development processes and personalized medicine.

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LIST OF PARTICIPANTS

S.NO	NAME	COURSE
1	ALWIN AMBUROZE A	M.PHARM (I SEM PHARM.CHEMISTRY
2	DHIVYA K	M.PHARM (I SEM PHARM.CHEMISTRY
3	JEEVANRAJ S	M.PHARM (I SEM PHARM.CHEMISTRY
4	KOSHILA K S	M.PHARM (I SEM PHARM.CHEMISTRY
5	LOGANANTHAM P	M.PHARM (I SEM PHARM.CHEMISTRY
6	MAHARAJOTHI P A	M.PHARM (I SEM PHARM.CHEMISTRY
7	PORSELVI R	M.PHARM (I SEM PHARM.CHEMISTRY
8	RASIKA T	M.PHARM (I SEM PHARM.CHEMISTRY
9	SOWMIYA S	M.PHARM (I SEM PHARM.CHEMISTRY
10	SRIMATHI D	M.PHARM (I SEM PHARM.CHEMISTRY
11	ARUN KUMAR V	M.PHARM (I SEM PHARM.ANALYSIS)
12	ASWIN M	M.PHARM (I SEM PHARM.ANALYSIS)
13	CHERAN N	M.PHARM (I SEM PHARM.ANALYSIS)
14	JAYAANAND R	M.PHARM (I SEM PHARM.ANALYSIS)
15	KAVIYARASAN D	M.PHARM (I SEM PHARM.ANALYSIS)
16	KEERTHIKUMAR V	M.PHARM (I SEM PHARM.ANALYSIS)
17	MANIKANDAN M	M.PHARM (I SEM PHARM.ANALYSIS)
18	NAVEEN KUMAR M	M.PHARM (I SEM PHARM.ANALYSIS)
19	RAJAMANICKAM P	M.PHARM (I SEM PHARM.ANALYSIS)
20	VARSHINI K	M.PHARM (I SEM PHARM.ANALYSIS)
21	NANDHINI.S	M.PHARM (I SEM PHARM.CHEMISTRY
22	RAJESH KUMAR S	M.PHARM (I SEM PHARM.CHEMISTRY
23	CHERAN K	M.PHARM (I SEM PHARM.ANALYSIS)
24	PRAVEEN RAJ K	M.PHARM (I SEM PHARM.ANALYSIS)
25	PRIYADHARSHINI.B	M.PHARM (I SEM PHARM.ANALYSIS)
26	SUBASH.V	M.PHARM (I SEM PHARM.ANALYSIS)
27	VAHITH E	M.PHARM (I SEM PHARM.ANALYSIS)
28	ABINAYA V	M.PHARM (I SEM PHARM.CHEMISTRY
29	ANITHA M	M.PHARM (I SEM PHARM.CHEMISTRY
30	DHIVYA K	M.PHARM (I SEM PHARM.CHEMISTRY

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31	MANISHA M	M.PHARM (I SEM PHARM.CHEMISTRY
32	PAVITHRA K	M.PHARM (I SEM PHARM.CHEMISTRY
33	PRIYANKA V	M.PHARM (I SEM PHARM.CHEMISTRY
34	SANTHANAKRISHNAN K	M.PHARM (I SEM PHARM.CHEMISTRY
35	SOJARNA K	M.PHARM (I SEM PHARM.CHEMISTRY
36	SUBHASHINI D	M.PHARM (I SEM PHARM.CHEMISTRY
37	SURYAMATHI P	M.PHARM (I SEM PHARM.CHEMISTRY
38	ABINAYA V	M.PHARM (I SEM PHARM.CHEMISTRY
39	AAKASH S	M.PHARM (I SEM PHARM.ANALYSIS)
40	ARUNPRAKASH S	M.PHARM (I SEM PHARM.ANALYSIS)
41	DEEPIKA R	M.PHARM (I SEM PHARM.ANALYSIS)
42	GOKULAKANNAN M	M.PHARM (I SEM PHARM.ANALYSIS)
43	HARSHA VARDHINEE K	M.PHARM (I SEM PHARM.ANALYSIS)
44	JAGADESWARAN C	M.PHARM (I SEM PHARM.ANALYSIS)
45	MARIMUTHU P	M.PHARM (I SEM PHARM.ANALYSIS)
46	RAGUNATH S	M.PHARM (I SEM PHARM.ANALYSIS)
47	SATHISH KUMAR V	M.PHARM (I SEM PHARM.ANALYSIS)
48	VISHNU M S	M.PHARM (I SEM PHARM.ANALYSIS)

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Principal

STUDENTS FEEDBACK ANALYSIS

DATE: 30/01/2024

Total marks = 50

S.NO	QUESTION DESCRIPTION	ANSWERS	MARKS	TOTAL MARKS
1	Satisfaction	Very satisfied	5	5
		Satisfied	3	
		Neutral	2	
		Dissatisfied	1	
		Very dissatisfied	0	
2	Clarity	Extremely clear	5	5
		Very clear	4	
		Moderately clear	2	
		Not very clear	1	
		Not at all clear	0	
3	Percentage of the information was new	100%	5	5
		75%	4	
		50%	3	
		25%	2	
		0%	1	
4	Informative	Extremely Informative	5	5
		Very Informative	3	
		Moderately Informative	2	
		Not very informative	1	
		Not informative at all	0	
5	Technical issues	Yes	5	5
		No	0	
6	Like to learn more about this topic	Yes	5	5

		No	0	
7	Rate the content of the slides/virtual aid	Extremely clear	5	5
		Very clear	3	
		Moderately clear	2	
		Not very clear	1	
		Not at all clear	0	
8	Accuracy of the sessions	Extremely clear	5	5
		Very clear	3	
		Moderately clear	2	
		Not very clear	1	
		Not at all clear	0	
9	Session expectations	Excellent	5	5
		Good	3	
		Fair	2	
		Poor	1	
		Not at all clear	0	
10	Rate the content of the seminar	1	1	5
		2	2	
		3	3	
		4	4	
		5	5	

Head of the Department

Principal

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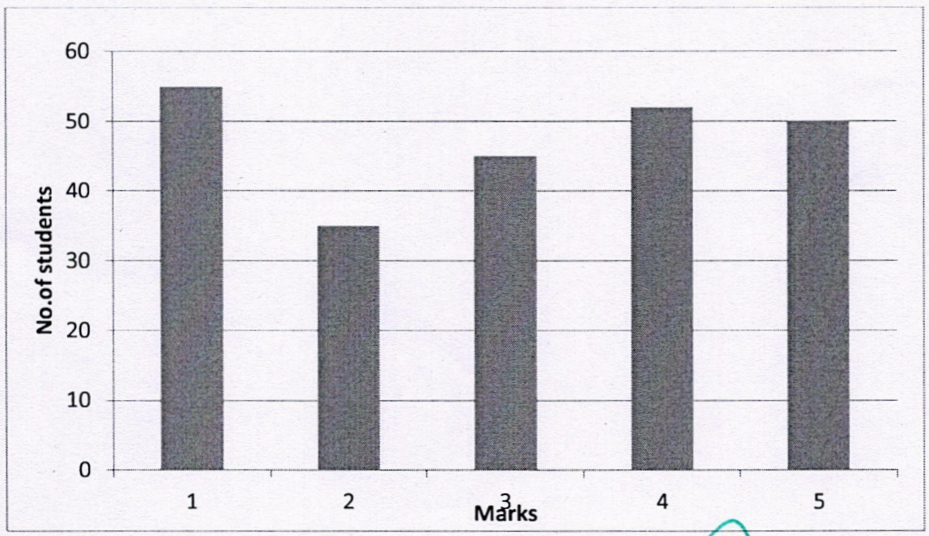
Feedback Question Analysis – Question Asked-Feedback Rating

1.Satisfaction	6.Like to learn more about this topic
2.Clarity	7.Rate the content of the slides/virtual aid
3. Percentage of the information was new	8.Accuracy of the sessions
4.Informative	9.Session expectations
5.Technical issues	10.Rate the content of the seminar



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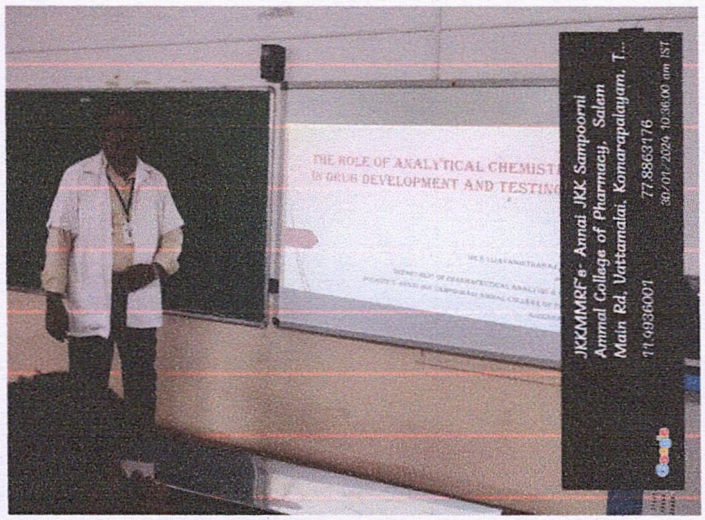
TITLE: THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING

DATE: 30.01.2024

Resource Person Interact with Students



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JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY

One day seminar on

THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING

Organized by

DEPARTMENT OF PHARMACEUTICAL ANALYSIS AND INTERNAL QUALITY ASSURANCE CELL(IQAC)

CERTIFICATE OF PARTICIPATION

This is to certify that MR./MS./MRS. _____

for participated in the seminar titled on " THE ROLE OF ANALYTICAL CHEMISTRY IN DRUG DEVELOPMENT AND TESTING" IN JKKMMRF'S -ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY, KOMARAPLAYAM ON 30th JANUARY 2024

CO- CONVENOR

CONVENOR