RBVRR WOMEN'S COLLEGE OF PHARMACY

 # 3-4-343, Barkathpura, Hyderabad – 5000 027 (T.S), India

Office: +91 40-27563065, Mobile: +91 9848930555

(Approved by the AICTE, PCI & Affiliated to Osmania University)

Recognized under section 2(f) of the UGC Act 1956

EAMCET Code: RBVW | PGECET Code: RBVW1

www. Rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com **&** rbvrrwcp2006@gmail.com

Invites you to the

Certificate Course on

"PROFESSIONAL DEVELOPMENT"

10th July 2018, 10:30 Am

Venue: Seminar Hall

Chief Guest:

Prof. R. Limbadri
Chairman
Telangana State Council
For Higher Education,
Telangana State, India

Guest of Honor:

Prof. K. Muthyam Reddy

Hon. Secretary &
Correspondent
RBVRR Women's
College Of
Pharmacy

Principal: Prof. M. Sumakanth

Programme Schedule

DATE	SPEAKER
10th – 11th Jul 2018	**Prof. Purushottam Reddy** Retd. Professor Osmania University
12th – 13th Jul 2018	**Ramakrishna Sistla** Senior Scientist IICT
14th – 15th Jul 2018	**Prof. M. Sumakanth** Principal RBVRR Women's College Of Pharmacy
16th – 17th Jul 2018	**P. Anuradha Reddy**

College Code: 1706

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Value Added Course		
Course: PROFESSIONAL DEVELOPMENT		
Code: PDC001	**Credits:** 2	**Total No. of Hours:** 36

Introducing Professional development skills as a course to students helps them to succeed in their academic and personal lives, build up strong relationships, and improve their overall well-being. Professional development skills are not only for personal growth but also for professional success. These courses cover a wide range of topics, from leadership skills to technical skills. Below is an outline that covers the basic aspects of various types of Professional Development Skills.

Course Objectives:

The Professional development skills course objective is to create oneself aiming at advancing their career and enhancing their skills and talents in the workplace.

The specific course objectives provides, explores and familiarize the students with insights on Time Management, Advanced writing skills, Interview skills, Leadership skills and Research skills which are important for building up their career.

Professional development skills refer to the abilities and traits that help individuals grow and improve. Here are some reasons why professional development skills matter for individuals:

1. ### Improved Self-Awareness

   Personal development skills help students become more self-aware. This means understanding their strengths, weaknesses, values, and goals. By developing self-awareness, students can make better decisions and find more fulfillment in their lives.

2. ### Better Communication

   By developing communication skills, students can improve their relationships with peers, professors, and future employers.

3. ### Goal Setting and Time Management

   College students have a lot on their plates, from coursework to extracurricular activities. By developing goal-setting and time-management skills, students can prioritize their tasks and make the most of their time.

4. ### Adaptability and Resilience

   Life is unpredictable, and students will inevitably face challenges and setbacks. By developing adaptability and resilience, students can bounce back from setbacks and overcome obstacles.

   By the end of the program, participants will be aware about all that are required for their career development i.e from leadership skills to technical skills.

Unit 1	Time Management	6 Hours

Time Management:
What Is Time Management, Why Time Management Is Important.
Setting Goals:
Goals and Targets, Setting SMART Goals, Your Own SMART Goals
Planning Tips and Tricks:
Planning Tools
Setting Priorities
Prioritizing Your Tasks
Your To-Do List
Managing Interruptions and Distractions
Tips for Controlling Disruptions

Unit 2	Advanced Writing Skills	7 Hours

The C's of Writing:
Writing Clearly, Writing Concisely, Making Connections ,Writing Correctly, Choosing Your Sources
Writing Mechanics:
Building Paragraphs, Proper Paragraphs, More on Paragraphs, Making Connections
Dealing with Specific Requests:
Types of Letters, Keeping it Real
Preparing Business Documents:
Requests for Proposals, The Proposals, The Differences When Writing Proposals, Ten Steps of Proposal Writing, Writing Reports, Documentation

Unit 3	Interview Skills	5 Hours

Interview Skills: Purpose of an interview, Do's and Dont's of an interview , E-Mail etiquette
Giving Presentations: Dealing with Fears, planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery
Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

Unit 4	Leadership Skills	9 Hours

Introduction to Leadership: Roles, functions and characteristics of a leader; evolution and growth of leadership; Leadership traits and ethics; Attitude, Behaviour, Personality traits and leadership; Types and Styles of leadership
Leadership and Management: Nature, Scope and Significance of Management; Levels of Management; Functions: Planning, Organizing, Staffing, Directing and Controlling; Skills: Conceptual, Human and Technical; Roles: Interpersonal, Informational and Decisional; difference between a leader and a manager
Theories of Leadership: Trait Theory, Behavioural theories, Contingency Theories, Transactional Theories and Transformational Leadership Theory
Issues and Challenges for Leaders: Immerging trends in leadership; Servant leadership, Situational leadership; Gender and leadership; Effective Leadership Communication; Emotional intelligence and leadership

Unit 5	Research Skills	9 Hours

Introduction to Research and Research Design
Nature and scope of research, information based decision making and source of knowledge. The research process; basic approaches and terminologies used in research. Defining research question and framing of hypotheses, Preparing a research plan, qualitative and quantitative research designs, Experimentation, Observational studies, Exploring secondary data.

Measurement and Scaling, Data Source and Data Collection

Field research; primary data collection from observations, surveys and experimentation. Measurement and scaling; commonly used scales in reliability and validity of scales. Designing instrument for data collection; testing the instrument, data collection process, Sampling methods and procedures and sample size decisions.

Data Analysis

Editing and coding of data, tabulation, graphic presentation of data, cross tabulation, Testing of hypotheses; type I and II errors, one tailed and two tailed tests of significance, Parametric and nonparametric tests for Univariate and Bivariate data. Tests of association; simple linear regression and other nonparametric tests.

Report Writing and Presentation

Professional Development Course Outcomes:

After the successful completion of this module the learners will be able to inspire individuals, manage talent, influence, lead teams, resolve conflict, build trust, increase cooperation and enhance productivity.

1. Demonstrate knowledge of and apply the basic principles of productivity to their own life.
2. Identify personal priorities and goals.
3. Identify how to maximize their time in order to accomplish their goals both personally and professionally
4. Students can effectively manage the team as a team player.

Develop interview skills and Leadership qualities which Helps to develop criticalappreciation

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Barkatpura, Hyderabad- 500 027

CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 1& 2 (Session 1 &2)

1. Name of the participant and institute: issmath fatima.
2. Name of the institute: Rbvrr womens college of pharmacy
3. Email id of the participant: ismath99@gmail.com
4. How was the content delivered by the speaker? (Prof. Purushotham Reddy)
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average
5. How do you rate the session?
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average

6. Time Management is essential in life

7. Process of time management starts with
   a) Cost your time
   b) ✓ Making activity logs
   c) Goal setting
   d) All of the above

8. Consequences of bad time management is fail to achieve goals

9. Making activity log helps in?
   a) Making realistic estimate of time spent
   b) Pinpoint the critical areas
   c) Finding high yielding jobs
   d) ✓ All of the above

10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - ○ No
    - ○ Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 1& 2 (Session 1 &2)

1. Name of the participant and institute: Manasa Reddy
2. Name of the institute: RBVRR Women's College of Pharmacy
3. Email id of the participant: manasareddy12@gmail.com.
4. How was the content delivered by the speaker? (Prof. Purushotham Reddy)
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average
5. How do you rate the session?
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average
6. Time Management is essential in life
7. Process of time management starts with
   a) Cost your time
   b) ✓ Making activity logs
   c) Goal setting
   d) All of the above
8. Consequences of bad time management is fail to achieve goals
9. Making activity log helps in?
   a) Making realistic estimate of time spent
   b) Pinpoint the critical areas
   c) Finding high yielding jobs
   d) ✓ All of the above
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - ○ No
    - ○ Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 3&4 (Session 1&2)

1. Name of the participant and institute: Brunda Sree
2. Name of the institute: RBVRR womens college of pharmacy
3. Email id of the participant : Brundasree@gmail.com
4. How was the content delivered by the speaker? (Ramakrishna Sistla)
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
6. Leadership is defined as guide to followers
7. What are the most important roles of a good leader?
   a) Motivational Team Members
   b) A Good Communicator
   c) Unity
   d) ✓ All of the above
8. Skills that are essential for a good leader?
   a) Conceptually skilled
   b) Diplomatic and tactful
   c) Socially skilled
   d) ✓ All the above
9. Cognitive resource theory focuses on Intelligence, experience, skills
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - o No
    - o Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 3&4 (Session 1&2)

1. Name of the participant and institute: Atika Fatima
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : fatimaunisaAtika@gmail.com
4. How was the content delivered by the speaker? (Ramakrishna Sistla)
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average
5. How do you rate the session?
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average
6. Leadership is defined as guide to followers
7. What are the most important roles of a good leader?
   a) Motivational Team Members
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8. Skills that are essential for a good leader?
   a) Conceptually skilled
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   d) ✓ All the above
9. Cognitive resource theory focuses on intelligence, experience, skills.
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - ○ No
    - ○ Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 5&6 (Session 1&2)

1. Name of the participant and institute: Priyanka .
2. Name of the institute: RBVRR WCOP
3. Email id of the participant: Priyankamenugu@gmail.com
4. How was the content delivered by the speaker? (Prof. M. Sumakanth)
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average
5. How do you rate the session?
   - ○ Excellent
   - ✓ Very Good
   - ○ Good
   - ○ Average
6. Observational Studies include -
   a) Cohort studies
   b) Case control studies
   c) Cross control studies
   d) ✓ All the above
7. By controlling the conditions, experimental studies establish Independant
8. Key features of Experimental studies are-
   a) Randomized Controlled trials
   b) ✓ Control groups
   c) None of the above
   d) All of the above
9. Observational research studies involve gathering data
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - ○ No
    - ○ Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 5&6 (Session 1&2)

1. Name of the participant and institute: Maseera Shakir
2. Name of the institute: RBVRR WCOP
3. Email id of the participant: shahmaheera@gmail.com
4. How was the content delivered by the speaker? (Prof. M. Sumakanth)
   - ✓ Excellent
   - Very Good
   - Good
   - Average
5. How do you rate the session?
   - Excellent
   - Very Good
   - ✓ Good
   - Average
6. Observational Studies include -
   a) Cohort studies
   b) Case control studies
   c) Cross control studies
   d) ✓ All the above
7. By controlling the conditions, experimental studies establish Independent
8. Key features of Experimental studies are-
   a) Randomized Controlled trials
   b) Control groups
   c) None of the above
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9. Observational research studies involve gathering data
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - No
    - Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 7 (Session 1&2)

1. Name of the participant and institute : Shruthi
2. Name of the institute: RBVRR College of pharmacy
3. Email id of the participant : Shruthiyas@gmail.com
4. How was the content delivered by the speaker? (P. Anuradha Reddy)
   - ✓ Excellent
   - Very Good
   - Good
   - Average
5. How do you rate the session?
   - ✓ Excellent
   - Very Good
   - Good
   - Average
6. Smart goals are to provide better understanding, are very good
7. Goal setting include-
   a) Process
   b) Performance
   c) Outcome
   d) ✓ All of the above
8. Goal setting helps in
   a) Setting a realistic timeline for the goal accomplishment
   b) Provide a better understanding of expectations
   c) ✓ Give clarity to decision making
   d) All of the above
9. Setting goals is important because it allows us to be creative
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - No
    - Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 7 (Session 1&2)

1. Name of the participant and institute : thati bhagya
2. Name of the institute: Rbvrr womens college.
3. Email id of the participant : thati bhagya@gmail.com
4. How was the content delivered by the speaker? (P. Anuradha Reddy)
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average
5. How do you rate the session?
   - ✓ Excellent
   - ○ Very Good
   - ○ Good
   - ○ Average
6. Smart goals are to provide better understanding all-very good
7. Goal setting include-
   a) Process
   b) Performance
   c) Outcome
   d) ✓ All of the above
8. Goal setting helps in
   a) Setting a realistic timeline for the goal accomplishment
   b) Provide a better understanding of expectations
   c) ✓ Give clarity to decision making
   d) All of the above
9. Setting goals is important because it allows us to be creative
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    - ✓ Yes
    - ○ No
    - ○ Maybe

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A 10 DAY CERTIFICATE COURSE IN PHARMACOVIGILANCE

2018

In Association with our Training Partner:

CLINOSOL™

A CLINICAL RESEARCH CAREER CATALYST

COURSE BENEFITS

- **Career Guidance and Resume Writing Skills**
- **Intensive 36-Hour Training by Industry Experts**
- **Hands-on Real-Time Practice Completion Certificate.**

Registration Fee - Rs 1000/-

Last Date for Registration:

27th Oct 2018

Payment: Gpay to 7416614919

About ClinoSol:

Founded in 2019, ClinoSol is a dynamic and forward-thinking healthcare company dedicated to transforming the way medical solutions are delivered. With a strong focus on innovation, ClinoSol has emerged as a pioneer in the industry, continuously striving to improve patient outcome and enhance healthcare systems globally. ClinoSol's products and services are tailored to serve the industry needs, thus, students can benefit from engaging with ClinoSol's professional tone of voice as they explore the innovative advancements in healthcare.

About RBVRR Women's College of Pharmacy

RBVRR Women's College of Pharmacy, founded in the year 2006, operates successfully under Hyderabad Mahila Vidhya Sangam, guided by the visionary leadership of its Founder Principal, Prof. M. Sumakanth, with a core mission of offering education to young women. The college has spacious classrooms, well-equipped laboratories with the latest equipment, and well-furnished seminar hall, conference room and library with a good number of the latest editions of both textbooks and reference books. The college is recognized as research centre by Osmania University. The college is offering the following courses:

- B.Pharmacy (100seats)
- Pharm. D (32 seats)
- M.Pharmacy (Pharma.Chemistry, Pharmaceutics, Pharm. Analysis and Pharmacology).

About the Course

- The 10-Day Hands-on Certificate course in Pharmacovigilance aims to provide participants with a comprehensive understanding of pharmacovigilance principles and practices.
- Through interactive sessions and practical exercises, attendees will learn about the importance of drug safety monitoring, adverse event reporting, and risk management strategies.
- The workshop will also cover the regulatory framework surrounding Pharmacovigilance and the role of various stakeholders in ensuring drug safety.
- Assist students in selecting a career path in pharmacovigilance.

SCHEDULE AND SYLLABUS

DATE	MODULE #	TOPIC	SPEAKER	DURATION
29th Oct 2018	Module 1	Introduction to Clinical Research and Pharmacovigilance	C.S Mujeebuddin	4 Hours
30th Oct 2018	Module 2	Case processing workflow	C.S Mujeebuddin	4 Hours
31st Oct 2018	Module 3	Causality Assessment	C.S Mujeebuddin	4 Hours
01st Nov 2018	Module 4	Expedited Reporting	C.S Mujeebuddin	3 Hours
02nd Nov 2018	Module 5	Narrative Writing	Dr. Mitesh Reddy	4 Hours
03rd Nov 2018	Module 6	Medical Coding in PV	Dr. Mitesh Reddy	3 Hours
05th Nov 2018	Module 7	Signal Management	Uma Priya	3 Hours
06th Nov 2018	Module 8	Aggregate Reporting	Uma Priya	4 Hours
07th Nov 2018	Module 9	Hands on Exercises	Uma Priya	4 Hours
08th Nov 2018	Module 10	Hands on Exercises and Assessment	Uma Priya	4 Hours

An Intensive Practice based Certification Course on		
PHARMACOVIGILANCE		
Code:PVCC001	Credits: 2	Course duration:36hrs

This certificate course is designed to equip participants with a deep understanding of pharmacovigilance principles, methodologies, and practical applications. This course is an unique blend of theoretical knowledge and practical skills, providing participants with a solid foundation for a successful career in pharmacovigilance.

OBJECTIVE: This course is exclusively designed for Graduates in Pharmacy and Bio-Sciences, Medical Professionals, junior professionals in Pharmaceutical and IT Industry and also for B.Pharm, Pharm D, M.Pharm pursuing students and to embrace the tactical aspects of Pharmacovigilance.

SYLLABUS

Module I	**Introduction to Pharmacovigilance**	**4hrs**
Introduction to Clinical Research and Pharmacovigilance. Historical perspectives and Current Status of pharmacovigilance. National and international aspects of PV.		
Module II	**Case Processing Workflow**	**4hrs**
Adverse Drug Reactions - Types, detection and reporting methods. Sources of Cases: Unsolicited Reports, Solicited reports, contractual agreements, Regulatory Authorities, Steps in case processing.		
Module III	**Causality Assessment**	**4hrs**
Factors Considered in Causality Assessment, Methods and Tools for Causality Assessment, Methods and Tools for Causality Assessment, Case studies.		
Module IV	**Expedited Reporting**	**3hrs**
Types of Regulatory reporting, Criteria for Expedited Reporting, Time Frames, Channels of reporting, Regulatory obligations.		
Module V:	**Narrative Writing**	**4hrs**
Narrative Writing objectives, regulatory frame work, Template of narrative writing. Case Studies.		
Module VI	**Medical Coding in PV**	**3hrs**
Medical coding: Introduction, WHO adverse reactions, terminologies, Med DRA and Standardized Med DRA.		
Module VII	**Signal Management**	**3hrs**
Signal terminologies, Methods of signal detection. Signal Management process flow, Qualitative and Quantitative signal detection, Analysis of different data sources.		
Module VIII	**Aggregate Reporting**	**4hrs**
Types of aggregate reporting , Reporting intervals, communication to regulatory authorities		
Module IX	**Practical session on Narrative Writing.**	**4hrs**
Exercises on Spontaneous reports,		
Module X	**Practical session on Causality assessment and Med DRA**	**4hrs**
Assessment of Causality based on Naranjo scale for the given cases, Med DRA Coding Demo		

COURSE OUT COMES

After completion of this course Participants can

1. Understand the basics of Pharmacovigilance and current status of Indian and Global Pharmacovigilance.
2. Explain Qualitative and Quantitative signal detection and perform Signal detection and management.
3. Gain insights into the significance of adverse event reporting and effective risk management strategies in the pharmaceutical industry
4. Equip with valuable knowledge and skills, fostering understanding of pharmacovigilance principles and preparing them for potential careers in this field.
5. Familiarize with real-world pharmacovigilance scenarios through Hands-on training sessions.

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CERTIFICATE COURSE ON PHARMACOVIGILANCE 2018

FEEDBACK FORM

1. Name of the participant: C. Pragnya
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : pragnyachilumuri@gmail.com
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. _____ is the building block of pharmacovigilance
   a. PvPI
   b. Clinical study reports
   c. Non-Clinical study reports
   d. ICSR
7. Periodic safety report is also called as ~~PSSR~~ periodic benefit risk evaluation report
8. what is the initial step to isoniazide toxicity?
   a. Liver function test
   b. MRI
   c. FMRI
   d. CBP
9. Would you like to attend more sessions like this?
   a. Yes
   b. No

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CERTIFICATE COURSE ON PHARMACOVIGILANCE 2018

FEEDBACK FORM

1. Name of the participant: Asma fatima
2. Name of the institute: RBVRR women's college of Pharmacy
3. Email id of the participant : fatimasma@gmail.com
4. How was the content delivered by the speaker?
   - a. Excellent
   - b. Very Good
   - c. Good
   - d. Average
5. How do you rate the session?
   - a. Excellent
   - b. Very Good
   - c. Good
   - d. Average
6. _____ is the building block of pharmacovigilance
   - a. PvPI
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7. Periodic safety report is also called as Periodic benefit risk assessment
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   - a. Yes
   - b. No

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Certificate course on

GREEN CHEMISTRY IN DRUG DISCOVERY-2018

AIM:

This certificate course aims to enhance understanding about the importance of green chemistry in medication design and development. The course focuses on the fundamentals of green chemistry, design, alternative energy sources, green synthesis catalysis, and contemporary green chemistry developments.

COURSE BENEFITS:

- Learn about principles of green chemistry.
- Gain hands on training on microwave synthesizer.
- Learn about design of nano-catalysts and significance of phase transfer catalysts and Biocatalysts in drug discovery.

Registration Link: https://forms.gle/Yu9WvuzVo2LvQbjV8

Registration Fee: 1000/-

Last Date for Registration: 30th Nov 2018

G-pay Number: 7702236567

ABOUT RBVRR WOMEN'S COLLEGE OF PHARMACY

RBVRR Women's College of Pharmacy, founded in the year 2006, operates successfully under Hyderabad Mahila Vidhya Sangam, guided by the visionary leadership of its Founder Principal, Prof. M. Sumakanth, with a core mission of offering education to young women. The college has spacious classrooms, wellequipped laboratories with the latest equipment, and well-furnished seminar hall, conference room and library with a good number of the latest editions of both textbooks and reference books.

The college is offering the following courses:

1. B.Pharmacy (100seats)

2. Pharm. D (32seats)

3. M.Pharmacy (Pharma. chemistry, Pharmaceutics, Pharm. Analysis and Pharmacology)

VISION

To lead the way in impacting lives via a creative, tenacious, and caring approach to pharmacy education as a National Women's Pharmacy Professional.

MISSION

Besides from the traditional curriculum, RBVRRWCP empowers and prepares female students for success in a changing society through on-going awareness programs.

OBJECTIVES

- To familiarize with green chemistry.
- To learn about green reagents, green solvents, green catalysts and reaction conditions.
- To know about greener technologies and alternative energy sources.
- To learn about renewable resources and greenhouse effect.
- To know the importance of catalysis in green synthesis.
- To know various techniques in green chemistry based on current needs.
- To learn the various green techniques and the technology behind them.

Value added course		
Course: Green chemistry in drug discovery		
Code: GCDCC001	Credits: 4	Total No. of Hours: 36hrs.

SYLLABUS

UNIT I: PRINCIPLES AND CONCEPTS OF GREEN CHEMISTRY 6 HRS

Introduction, principles of green chemistry, sustainable development and green chemistry. Atom economic reactions - rearrangement and addition reactions. Atom un-economic reactions - substitution, elimination reactions.

UNIT II: DESIGNING A GREEN SYNTHESIS 7 HRS

Role of green synthesis in drug discovery Green discoveries; greener reagents, role of green catalysts in organic synthesis, Sustainable synthesis of pharmaceuticals. Development of Photo enzymatic Strategies for Selective Organic Synthesis—Focus on Advantages and Challenges

UNIT III: GREENER TECHNOLOGIES AND ALTERNATIVE ENERGY SOURCES 7 HRS

Chemistry using Microwaves: Microwave heating and microwave-assisted reactions in water, reactions in organic solvents, solvent free reactions. Sonochemistry & Electrochemical synthesis with examples.

UNIT IV: RENEWABLE RESOURCES AND GREENHOUSE EFFECT 8 HRS

Biomass as a renewable resource: Fossil fuels, biomass, solar power, fuel cells and other forms of renewable energy. Chemicals and polymers from renewable feedstock. Greenhouse effect and Global Warming - Introduction - How the greenhouse effect is produced - Major sources of greenhouse gasses - Emissions of CO2 - Impact of greenhouse effect on global climate. Control and remedial measures of greenhouse effect. Global warming- A serious threat to life on earth.

UNIT V: CATALYSIS IN GREEN SYNTHESIS. 8 HRS

The design of Nano-catalysts for energy and environmental applications. Phase Transfer Catalysts: Introduction, mechanism of catalytic action, type of catalysts and its advantages, Application of Phase transfer catalysis in green synthesis. Biocatalysts: Introduction, Biochemical oxidations and reductions.

PROGRAMME SCHEDULE:

DATE	Morning Session (10:00am – 01:00pm)	Afternoon session (01:30pm – :00pm)
03rd Dec 2018	Dr. Srinivas Nanduri Professor, Department of Chemical Sciences, NIPER Hyderabad	Dr. K. Premalatha Assistant Professor Department of Chemistry, University College for Women, Osmania University

04th Dec 2018	Dr. T. Saravanan Assistant Professor School of Chemistry University of Hyderabad Hyderabad.	Dr. Bhoomi Reddy Rama Devi Professor & Head of the Department, Chemistry JNTUH University College of Engineering, Science & Technology, Hyderabad.
05th Dec 2018	Dr. T. Saravanan Assistant Professor School of Chemistry University of Hyderabad Hyderabad.	Dr. Bhoomi Reddy Rama Devi Professor & Head of the Department, Chemistry JNTUH University College of Engineering, Science & Technology, Hyderabad.
06th Dec 2018	Hands on training	
07th Dec 2018	Dr. Srinivas Nanduri Professor, Department of Chemical Sciences, NIPER Hyderabad	Dr. K. Premalatha Assistant Professor Department of Chemistry, University College for Women, Osmania University
08th Dec 2018	Dr. Srinivas Nanduri Professor, Department of Chemical Sciences, NIPER Hyderabad	Dr. K. Premalatha Assistant Professor Department of Chemistry, University College for Women, Osmania University
10th Dec 2018	Prof. M. Sumakanth Principal, RBVRR Women's College of Pharmacy Valedictory Session	Prof. M. Sumakanth Principal, RBVRR Women's College of Pharmacy Valedictory Session

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Barkatpura, Hyderabad- 500 027

CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 1 SESSION – 1& 2 :

1. Name of the participant: Fariha Naaz
2. Name of the institute: rbvrrwcop.
3. Email id of the participant : _____

4. How was the content delivered by the speaker?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
6. At which part of the enzyme does the substrate fit in?
   - a) Left end
   - b) Right end
   - ✓ c) Active site
   - d) Binding site
7. The metal ions that binds the substrate and active site of the enzyme is called
   - a) Inhibitors
   - b) Coenzyme
   - ✓ c) Prosthetic group
   - d) Cofactors
8. Active site occupy less than 5 % of total surface of enzyme.
9. How are enzymes different from catalysts?
   - a) Enzymes are active at high temperatures
   - b) Catalysts are active at sub-zero temperatures
   - ✓ c) Catalysts are efficient at high temperatures and high pressures.
   - d) Enzymes are denatured at room temperature.
10. How many classes are enzymes divided into?
    a) 6 b)7 ✓ c)5 d) 8
11. Would you like to have more sessions like this ?
    - ✓ Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 1 SESSION – 1& 2 :

1. Name of the participant: C. Pragnya
2. Name of the institute: RBVRR womens college of pharmacy
3. Email id of the participant : –

4. How was the content delivered by the speaker?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
6. At which part of the enzyme does the substrate fit in?
   a) Left end
   b) Right end
   c) ✓ Active site
   d) Binding site
7. The metal ions that binds the substrate and active site of the enzyme is called
   a) Inhibitors
   b) Coenzyme
   c) ✓ Prosthetic group
   d) Cofactors
8. Active site occupy less than 10 % of total surface of enzyme.
9. How are enzymes different from catalysts?
   a) Enzymes are active at high temperatures
   b) Catalysts are active at sub-zero temperatures
   c) ✓ Catalysts are efficient at high temperatures and high pressures.
   d) Enzymes are denatured at room temperature.
10. How many classes are enzymes divided into?
    a) 6 b)7 c) ✓5 d) 8
11. Would you like to have more sessions like this ?
    - ✓ Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 2 :

1. Name of the participant and institute : G. Eshitha
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : –
4. How was the content delivered by the speaker?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. The most potent greenhouse gas in terms of efficiency is
   a) N_2O
   b) CO_2
   c) CFC
   d) CH_4
7. The atom economy obtained for green synthesis in the range of
   a) 62-70%
   b) 72-82%
   c) 40-50%
   d) 90-100%
8. Green synthesis method is _____than the conventional method.
   a) Most costlier b) More efficient c) Slower d) Less efficient.
9. Which of the following reaction is atom economic reaction?
   a) Addition b) Substitution c) Rearrangement d) Elimination.
10. Would you like to have more sessions like this ?
    - o Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 2 :

1. Name of the participant and institute : Hadia Khanam
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average

6. The most potent greenhouse gas in terms of efficiency is
   a) N_2O
   b) CO_2
   c) CFC
   d) CH_4
7. The atom economy obtained for green synthesis in the range of
   a) 62-70%
   b) 72-82%
   c) 40-50%
   d) 90-100%
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   a) Most costlier b) More efficient c) Slower d) Less efficient.

9. Which of the following reaction is atom economic reaction?
   a) Addition b) Substitution c) Rearrangement d) Elimination.

10. Would you like to have more sessions like this ?
    - ✓ Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 3

1. Name of the participant: J. durgeshwari
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   - a. ✓ Excellent
   - b. Very Good
   - c. Good
   - d. Average
5. How do you rate the session?
   - a. Excellent
   - b. ✓ Very Good
   - c. Good
   - d. Average
6. The selection of reagent is made on basis of
   - a) Efficiency
   - b) Availability
   - c) its effect on environment
   - d) ✓ All the above
7. What is Microencapsulated Lewis acid can be reused upto 10 times.
8. Enzymatic fermentation is used for production of Antibiotics.
9. When Biochemical reactions are
   - a) Chemo selective
   - b) Regio selective
   - c) Stereo selective
   - d) ✓ All the above.
10. Would you like to attend more sessions like this?
    - ✓ Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 3

1. Name of the participant: Matiha shakeel
2. Name of the institute: rbvrrwcop
3. Email id of the participant : -
4. How was the content delivered by the speaker?
   - a. ✓ Excellent
   - b. Very Good
   - c. Good
   - d. Average
5. How do you rate the session?
   - a. Excellent
   - b. ✓ Very Good
   - c. Good
   - d. Average
6. The selection of reagent is made on basis of
   - a) Efficiency
   - b) Availability
   - c) its effect on environment
   - d) ✓ All the above
7. What is Microencapsulated Lewis acid can be reused upto 12 times.
8. Enzymatic fermentation is used for production of Antibiotics.
9. When Biochemical reactions are
   - a) Chemo selective
   - b) Regio selective
   - c) ✓ Stereo selective
   - d) All the above.
10. Would you like to attend more sessions like this?
    - ✓ Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 4

1. Name of the participant: Hindya reddy
2. Name of the institute: RBVRR women's college of pharmacy
3. E mail id of the participant: _____
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. Which of the following source of energy can be replenished after a short period of time?
   a. Solar energy
   b. Hydro energy
   c. Coal
   d. Both a and b
7. Greenhouse effect is due to _____ layer in the atmosphere?
   a. Ozone
   b. Infrared
   c. Moisture
   d. Carbon dioxide
8. Which Burning of fossil fuels results in
   a. Increased oxygen levels
   b. Decreased greenhouse gases
   c. Increased greenhouse gases
   d. Increased ethane level
9. Which of the following has maximum global warming potential?
   a. Methane
   b. Carbon dioxide
   c. Nitrous oxide
   d. Carbon monoxide.
10. Would you like to attend more sessions like this?
    a. Yes

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FEEDBACK FORM DAY – 4

1. Name of the participant : S Madhavi
2. Name of the institute: rbvrrwcop.
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   a. ✓ Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. ✓ Very Good
   c. Good
   d. Average
6. Which of the following source of energy can be replenished after a short period of time?
   a. Solar energy
   b. Hydro energy
   c. Coal
   d. ✓ Both a and b
7. Greenhouse effect is due to _____ layer in the atmosphere?
   a. Ozone
   b. ✓ Infrared
   c. Moisture
   d. Carbon dioxide
8. Which Burning of fossil fuels results in
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   b. Decreased greenhouse gases
   c. ✓ Increased greenhouse gases
   d. Increased ethane level
9. Which of the following has maximum global warming potential?
   a. Methane
   b. ✓ Carbon dioxide
   c. Nitrous oxide
   d. Carbon monoxide.
10. Would you like to attend more sessions like this?
    a. ✓ Yes

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 5

1. Name of the participant: Kulsum fatima abdi
2. Name of the institute: RBVRR WCOP
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. What are cofactors?
   A- Non-protein part, that is required for protein is biogical activity.
7. Which of these enzymes are not proteinaceous?
   a. Kinases
   b. Endonucleases
   c. Ligases
   d. Ribozymes
8. Which enzyme is used in the production of sitagliptin?
   a. Ligases
   b. Isomerases
   c. Transaminases
   d. Transferases
9. Reductases are used to reduce activated alkene bonds in chiral fashion.
10. Would you like to attend more sessions like this?
    a. Yes
    b. No
    c. Maybe

b. No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 5

1. Name of the participant: Iqra mustafa.
2. Name of the institute: RBVRRWCOP
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. What are cofactors?
   A Non-protein part that is required for protein is biological activity.
7. Which of these enzymes are not proteinaceous?
   a. Kinases
   b. Endonucleases
   c. Ligases
   d. Ribozymes
8. Which enzyme is used in the production of sitagliptin?
   a. Ligases
   b. Isomerases
   c. Transaminases
   d. Transferases
9. Ene-reductases are used to reduce activated alkene bonds in chiral fashion.
10. Would you like to attend more sessions like this?
    a. Yes
    b. No
    c. Maybe

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 6

1. Name of the participant: Sania khan
2. Name of the institute: RBVRR W COP
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   a. ✓ Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. ✓ Very Good
   c. Good
   d. Average
6. What is a catalyst?
   The substance which alters the speed of reaction.
7. Nanomaterial's are the materials with at least one dimension measuring less than ?
   a. 1nm
   b. 10nm
   c. ✓ 100nm
   d. 1000nm.
8. What are different dopants used for ceria
   a. Zr^{4+}
   b. Hf^{4+}
   c. ✓ Ti^{4+}
   d. All of them.
9. Which gas combines with the haemoglobin and hinders the oxygen transport
   a. Carbon dioxide
   b. ✓ Carbon monoxide
   c. SO_2
   d. N_2O
10. Would you like to attend more sessions like this?
    a. ✓ Yes
    b. No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 2018

FEEDBACK FORM DAY – 6

1. Name of the participant: G. Sai nikitha.
2. Name of the institute: rbvrr women's college of pharmacy.
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   - a. ✓ Excellent
   - b. Very Good
   - c. Good
   - d. Average
5. How do you rate the session?
   - a. Excellent
   - b. ✓ Very Good
   - c. Good
   - d. Average
6. What is a catalyst?
   The substance which alters the speed of reaction.
7. Nanomaterial's are the materials with at least one dimension measuring less than ?
   - a. 1nm
   - b. 10nm
   - c. ✓ 100nm
   - d. 1000nm.
8. What are different dopants used for ceria
   - a. Zr^{4+}
   - b. Hf^{4+}
   - c. Ti^{4+}
   - d. ✓ All of them.
9. Which gas combines with the haemoglobin and hinders the oxygen transport
   - a. Carbon dioxide
   - b. ✓ Carbon monoxide
   - c. SO_2
   - d. N_2O
10. Would you like to attend more sessions like this?
    - a. ✓ Yes
    - b. No

College Code: 1706

RBVRR WOMEN'S COLLEGE OF PHARMACY

3-4-343, Barkathpura, Hyderabad - 500 027 (T.S), India

Office: +91 40-27563065, Mobile: +91 9848930555

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Recognized under Section 2(f) of the UGC Act 1956

EAMCET Code: RBVW | PGECET Code: RBVW1

www.rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com & rbvrrwcp2006@gmail.com

Certificate Course on

Design of Experiment in Pharmaceutical Development

11th- 16th June, 2018

At RBVRR Women's College of Pharmacy

Seminar Hall

INAUGRAL SESSION:

Dr. K.V. Ratnamala

Associate Prof, Dept of Pharmaceutics

RBVRR Women's College of Pharmacy

PATRON

Dr.k. Muthyam Reddy

Hon. Secretary cum Correspondent

RBVRR Women's College of pharmacy

CONVENER:

Prof. M. Sumakanth

Principal

RBVRR Women's College of pharmacy

Speaker	Date & time
1. Dr. K.V. Ratnamala **Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy**	Session-1: 11th June 2018 at 11:00 am Session-2: 11th June 2018 at 2.00 pm Session-1: 12th June 2018 at 11:00 am Session-2: 12th June 2018 at 2.00 pm
2. Dr. G. Uma Rani **Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy**	Session-1: 13th June 2018 at 11:00 am Session-2: 13th June 2018 at 2.00 pm Session-1: 14th June 2018 at 11:00 am Session-2: 14th June 2018 at 2.00 pm
3. Dr. A. Krishna Sailaja **Professor & Head, Dept. of Pharmaceutics, RBVRR Women'sCollege of Pharmacy**	Session-1: 15th June 2018 at 11:00 am Session-2: 15th June 2018 at 2.00 pm Session-1: 16thJune 2018 at 11:00 am Session-2: 16thJune 2018 at 2.00 pm

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3-4-343, Barkathpura, Hyderabad - 500027, Ph: 040-27563065
(Approved by AICTE & PCI, Accreditated by NBA (B Pharmacy Course) Affiliated Osmania University
EAMCET Code: RBVW | PGECET Code: RBVW1

Value Added Course		
Course: Certificate course on design of experiment in pharmaceuticaldevelopment		
Code: DOE C001	**Credits:** 2	**Total No. of Hours :**36

A certificate course in Design of Experiments (DOE) for pharmaceutical development provides participants with a comprehensive understanding of experimental design principles tailored to the industry's specific needs. Through this program, individuals learn to optimize processes, reduce variability, and elevate product quality by implementing efficient experimental designs. The course fosters informed decision-making, facilitates cost reduction through streamlined experimentation, and accelerates time to market for new pharmaceutical products. Moreover, it cultivates a culture of continuous improvement within organizations, promoting competitiveness and adherence to regulatory standards. Graduates of this program are positioned for professional advancement and contribute to driving innovation and excellence in pharmaceutical development.

Objectives: The objectives of a certificate course in Design of Experiments (DOE) for pharmaceutical product development are to optimize processes, enhance product quality, improve efficiency, reduce costs, ensure regulatory compliance, facilitate data-driven decision-making, foster innovation, and support professional development

SYLLABUS:

UNIT 1	**INTRODUCTION**	**6 HRS**
Introduction basic need and Strategy of Experimentation, Typical applications of Experimental design, Basic Principles, Guidelines for Designing Experiments.		

Unit II	**Basic Statistical Concepts**	**7 HRS**
Basic statistical concepts covers Overview and applications of statistical methods which includes Measures of central tendency and variability.Probability Distributions: Normal, binomial, and Poisson,Confidence intervals, hypothesis testing.Correlation and Regression: Relationship between variables.Experimental Design: Basics and applications.Statistical Process Control (SPC): Monitoring manufacturing processes.Quality by Design (QbD): Principles and statistical tools.Software Applications: Hands-on experience with statistical software.		

UNIT III	**Experimental Design**	**7 HRS**
Experimental design covers Basics and objectives of experimental design,Hypothesis testing, ANOVA, regression,Full, fractional, and mixed factorial designsResponse Surface Methodology in Optimizing processes and formulations.Robust Parameter Design in Optimizing performance under uncertainty,Hands-on training with statistical software.Case Studies: Real-world applications in various fields.		

Unit IV	**Analysis And Interpretation Methods**	8 HRS
Introduction to Analytical Techniques,Data Interpretation Skills,Quality Control and Assurance,Regulatory CompliancesProblem-Solving Abilities,Risk Assessment and Mitigation,Communication Skills,Continuous Improvement		

Unit V	**Quality By Experimental Design**	8HRS

"Quality by Experimental Design" in pharmaceutical transdermal drug delivery system (TDDS) development:

1. Introduction to Quality by Design (QbD)
    - Overview of QbD principles and their importance in pharmaceutical development.
    - Application of QbD concepts to transdermal drug delivery systems.
2. Basics of Experimental Design
    - Understanding experimental design principles.
    - Types of experimental designs: full factorial, fractional factorial, and screening designs.
3. Factorial Designs for TDDS
    - Designing experiments to study the effects of multiple factors on TDDS performance.
    - Analysis of factorial experiments using statistical techniques.
4. Optimization Techniques
    - Response surface methodology (RSM) for optimizing TDDS formulations.
    - Desirability functions for multi-criteria optimization.
5. Risk Assessment and Mitigation
    - Identifying critical quality attributes (CQAs) and critical process parameters (CPPs) for TDDS.
    - Application of risk assessment tools in QbD for TDDS development.
6. Statistical Process Control (SPC) in TDDS Manufacturing
    - Monitoring and controlling TDDS manufacturing processes using SPC tools.
    - Control chart analysis for ensuring TDDS quality and consistency.
7. Case Studies and Applications
    - Analysis of real-world case studies demonstrating the application of QbD and experimental design principles in TDDS development.
    - Hands-on exercises and projects involving experimental design and optimization of TDDS formulations.
8. Regulatory Considerations
    - Understanding regulatory requirements and guidelines relevant to QbD implementation in TDDS development.
    - Documentation and reporting of QbD studies for regulatory submissions.

Design of experiments Course Outcomes:

After completion of this course

1.Students gain a solid understanding of fundamental statistical concepts such as hypothesis testing, analysis of variance (ANOVA), regression analysis, and statistical process control (SPC). This knowledge forms the foundation for applying statistical methods effectively in pharmaceutical development.

2.Students learn how to design and analyze experiments to optimize pharmaceutical formulations. By systematically varying factors like excipient concentrations or processing parameters, students can identify the optimal conditions for achieving desired product characteristics such as stability, bioavailability, and drug release profile.

3.Process Optimization Skills: Through DOE, students learn how to systematically optimize manufacturing processes to ensure product quality and consistency. They gain skills in identifying critical process parameters (CPPs) and understanding their impact on product quality attributes.

4.By applying statistical tools to real-world pharmaceutical problems, students develop problem-solving skills. They learn how to identify sources of variability, troubleshoot process issues, and implement data-driven solutions to improve product quality and process efficiency.
5. Preparation for Regulatory Requirements: Students understand the importance of statistical methods in meeting regulatory requirements for pharmaceutical development. By learning how to design experiments and analyze data rigorously, students are better prepared to support regulatory submissions and comply with guidelines such as those outlined by the International Council for Harmonisation (ICH).
6.Analysis and Interpretation Methods in Pharmaceutical Product Development is to equip students with the skills to effectively analyze and interpret data throughout the product development lifecycle. This includes understanding analytical techniques, applying statistical methods for quality control, ensuring regulatory compliance, enhancing problem-solving abilities, and improving communication
7.Students will gain a deep understanding of QbD principles, methodologies, and tools relevant to pharmaceutical and biopharmaceutical product development.

- Problem-Solving Skills: They will develop the ability to apply QbD concepts to solve complex problems in product formulation, process optimization, and quality control.
- Critical Thinking: Students will learn to critically evaluate processes and identify critical quality attributes (CQAs) and critical process parameters (CPPs) that impact product quality.
- Communication Skills: They will enhance their ability to communicate effectively with cross-functional teams, regulators, and stakeholders regarding QbD strategies, risk assessments, and quality control measures.
- Application in Real-world Scenarios: Students will be able to apply QbD principles to real-world scenarios, such as developing robust manufacturing processes, addressing regulatory requirements, and troubleshooting production issues.

- Regulatory Compliance: They will understand regulatory guidelines and expectations related to QbD implementation, ensuring compliance throughout the product lifecycle.
- Collaborative Work: Students will develop skills for collaboration and teamwork,working across disciplines to achieve common quality goals.
- Continuous Learning and Improvement: They will cultivate a mindset of continuous learning and improvement, adapting QbD strategies to evolving industry standards andtechnological advancements.

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EAMCET Code: RBVW | PGECET Code: RBVW1

Certificate course on by design of experiment in pharmaceutical development

FEEDBACK FORM DAY 1(session -1)

1.Name of the participant:.....Gowda Nikitha.....

2.Name of the institute:....RBVRR WCOP.....

3.Email address:.....

4.How was the content delivered by the speaker..

☑ excellent

□ very good

□ Good

5. How do you rate the session

☑ excellent

□ very good

□ Good

6. What is the primary purpose of experimentation in scientific research?

a) To prove a hypothesis b) To gather data and test hypotheses c) To support preconceived notions d) To confirm existing beliefs

7.Which of the following is NOT a basic need of experimentation? a) Reproducibility b) Control c) Randomness d) Bias

8.Which statistical method is commonly used to determine whether the results of an experiment are statistically significant?

a) T-test b) ANOVA c) Chi-square test d) Regression analysis

9.Randomization in experimentation helps to:

a) Ensure that all participants are identical b) Minimize the effects of confounding variables c) Increase bias in the results d) Simplify the experimental design

10.Which of the following is NOT a potential ethical concern in experimentation?

a) Informed consent b) Deception of participants c) Fabrication of data d) Harm to participants or society

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FEEDBACK FORM DAY 1(session -1)

1.Name of the participant: Shwetha

2.Name of the institute: RBVRR WCOP

3.Email address: Shwetha.kpharm@gmail.com

4.How was the content delivered by the speaker..

- excellent
- very good
- ✓ Good

5. How do you rate the session

- excellent
- very good
- ✓ Good

6. What is the primary purpose of experimentation in scientific research?

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FEEDBACK FORM DAY 1(session 2)

1.Name of the participant: B. Pranaya Rajini

2.Name of the institute: Rbvrr wcop

3.Email address: -

4.How was the content delivered by the speaker..

- ☐ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
- ☐ very good
- ☐ Good

6.What is the term for the phenomenon where participants' expectations or beliefs about an experiment affect their behavior?

a) Confirmation bias b) Placebo effect c) Hawthorne effect d) Observer bias

7.Which of the following is NOT a common type of experimental design?

a) Cross-sectional b) Longitudinal c) Correlational d) Experimental

8.Why is control important in an experiment?

a) To ensure that only one variable is changed at a time b) To make the experiment more complicated c) To confuse the participants d) To introduce bias

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FEEDBACK FORM DAY 1(session 2)

1 Name of the participant: Grashma

2 Name of the institute: RBVRR WCP

3 Email address: Grashma@gmail.com

4 How was the content delivered by the speaker..

- ☐ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
- ☐ very good
- ☐ Good

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FEEDBACK FORM DAY 2(session 1)

1 Name of the participant: B. Greeshma Paul

2 Name of the institute: RBVRRWCOP

3 Email address: -

4 How was the content delivered by the speaker

- ☐ excellent
- ☑ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
- ☑ very good
- ☐ Good

6.What is the purpose of randomization in experimental design?

☑ A) To ensure that all treatment groups are exactly the same B) To reduce the effects of confounding variables C) To increase the sample size D) To guarantee that the experiment will yield statistically significant results

7.Which of the following is NOT a common type of experimental design? A) Completely Randomized Design ☑ B) Matched Pairs Design C) Latin Square Design D) Sequential Design

8.What is a factorial experiment?

A) An experiment that involves only two levels of the independent variable B) An experiment that manipulates more than one independent variable C) An experiment conducted in a laboratory setting D) ☑ An experiment that uses a factorial analysis to analyze the data

9.Which of the following is a measure of the variability within treatment groups relative to the variability between treatment groups?

A) Mean Square Error (MSE) ☑ B) F-statistic C) Standard deviation D) T-statistic

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FEEDBACK FORM DAY 2(session 1)

1.Name of the participant:..Mithuraraju.....

2.Name of the institute:..RBVRRWP.....
3.Email address:..Mithuraraju@gmail.com.....
4.How was the content delivered by the speaker..
□ excellent
□ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
□ Good
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FEEDBACK FORM DAY 2(session 2)

1.Name of the participant: Uzma afreen

2.Name of the institute: rbvrrwcop

3.Email address:

4.How was the content delivered by the speaker..

□ excellent
□ very good
□ Good

5. How do you rate the session

□ excellent
□ very good
□ Good

6.What is the main advantage of a randomized complete block design (RCBD) over a completely randomized design (CRD)?

A) RCBD allows for the comparison of more than two treatments. B) RCBD reduces the variability within treatment groups. C) RCBD accounts for the variability between blocks. D) RCBD requires a smaller sample size.

7.In pharmaceutical product development, what is the primary purpose of a Phase III clinical trial?

A) To assess the safety and efficacy of the drug in a large population B) To determine the optimal dosage of the drug C) To investigate potential drug interactions D) To obtain regulatory approval for marketing the drug

8.Which statistical method is commonly used to determine the sample size for clinical trials in pharmaceutical product development?

A) Analysis of variance (ANOVA) B) Power analysis C) Chi-square test D) Student's t-test

9.What is the purpose of randomization in a clinical trial?

A) To ensure that participants are evenly distributed across treatment groups B) To prevent participants from dropping out of the study C) To control for confounding variables D) To increase the likelihood of obtaining statistically significant results

10.Which of the following is a measure of the precision of a clinical trial estimate?

A) Confidence interval B) P-value C) Odds ratio D) Hazard ratio

11.Which phase of clinical trials involves testing the drug in healthy volunteers to assess its safety and pharmacokinetics?

A) Phase I B) Phase II C) Phase III D) Phase

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FEEDBACK FORM DAY 2(session_2)

1 Name of the participant: Nidha Begum

2 Name of the institute: Rbvrr womens college of pharmacy

3 Email address: nidha.12s@gmail.com

4 How was the content delivered by the speaker..

- ☐ excellent
- ☐ very good
- ☐ Good

5 How do you rate the session

- ☐ excellent
- ☐ very good
- ☐ Good

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FEEDBACK FORM DAY 3(session_1)

1.Name of the participant: Sirisha

2.Name of the institute: RBVRRIOCOP.

3.Email address: Sirisha.bharda@gmail.com .

4.How was the content delivered by the speaker..

- □ excellent
- ☑ Very good
- □ Good

5. How do you rate the session

- □ excellent
- ☑ Very good
- □ Good

6 What is the primary goal of Quality by Design (QbD) in pharmaceutical manufacturing?

A) To minimize production costs B) To comply with regulatory requirements C) To ensure consistent product quality and performance D) To maximize production output

7.Which of the following is NOT a key principle of Quality by Design (QbD)?

A) Designing quality into the product B) Understanding and controlling the manufacturing process C) Continuously monitoring product quality during production D) Performing quality testing only at the final stage of production

8.What is the purpose of a Design of Experiments (DOE) in Quality by Design (QbD)? A) To optimize the manufacturing process parameters B) To identify critical quality attributes (CQAs) of the product C) To validate the manufacturing process D) To conduct stability testing on the finished product

9.Which statistical tool is commonly used to analyze the results of a Design of Experiments (DOE)?

A) Analysis of Variance (ANOVA) B) Regression analysis C) Chi-square test D) Student's t-test

10.What is the purpose of a risk assessment in Quality by Design (QbD)?

A) To identify potential failures in the manufacturing process B) To determine the acceptable quality limits for critical process parameters C) To evaluate the impact of process variability on product quality D) To ensure compliance with regulatory guidelines

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FEEDBACK FORM DAY 3(session_1)

1 Name of the participant: P.Narayanaiah.....

2 Name of the institute: RBVRRWCP.....
3 Email address: pnarayanaiah@rbvrrwcp.edu.in.....
4 How was the content delivered by the speaker..
□ excellent
✓ very good
□ Good
5 How do you rate the session
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FEEDBACK FORM DAY 3(session_2)

1 Name of the participant: Greeshma

2 Name of the institute: Kvrrwcop

3 Email address:

4 How was the content delivered by the speaker..

- ☐ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
- ☐ very good
- ☐ good

6.Which regulatory agency emphasizes Quality by Design (QbD) principles in its guidelines for pharmaceutical development?

A) International Conference on Harmonization (ICH) B) Food and Drug Administration (FDA) C) European Medicines Agency (EMA) D) World Health Organization (WHO)

7.What is the primary benefit of implementing Quality by Design (QbD) in pharmaceutical manufacturing?

A) Reduced production costs B) Improved product quality and consistency C) Faster time to market D) Increased manufacturing capacity

8.Which phase of Quality by Design (QbD) focuses on identifying and understanding the critical quality attributes (CQAs) of the drug product? A) Quality Risk Management B) Design Space C) Control Strategy D) Target Product Profile

9.What is the purpose of a Control Strategy in Quality by Design (QbD)?

A) To establish specifications for raw materials and finished products B) To continuously monitor and control critical process parameters C) To identify and mitigate potential risks in the manufacturing process D) To define the range of acceptable quality attributes for the product

10.Which of the following is NOT a component of the Quality by Design (QbD) framework?

A) Risk Assessment B) Design Space C) Quality Control D) Continuous Improvement

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FEEDBACK FORM DAY 3(session 2)

1.Name of the participant:.....D.Vishwanayani

2.Name of the institute:...RBVRRWCOP.....

3.Email address:.....

4.How was the content delivered by the speaker..

- ☐ excellent
- ☑ very good
- ☐ Good

5. How do you rate the session

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FEEDBACK FORM DAY 4(session 1)

1.Name of the participant: Asma Yl Husna.

2.Name of the institute: rbvrrwcop

3.Email address: asmalhs34@gmail.com

4.How was the content delivered by the speaker..

- ☐ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
- ☐ very good
- ☐ good

6.What is the purpose of a crossover design in pharmaceutical research?

A) To compare the efficacy of two or more treatments simultaneously B) To eliminate carryover effects from previous treatments C) To randomize participants into different treatment groups D) To increase the power of the statistical analysis

7.What is the purpose of a pilot study in experimental research?

A) To assess the feasibility and validity of the study design B) To obtain preliminary data for sample size calculation C) To identify potential confounding variables D) To ensure that participants are evenly distributed across treatment groups

8.What is the primary advantage of a factorial design in pharmaceutical research?

A) It allows for the comparison of more than two treatments simultaneously. B) It eliminates carryover effects from previous treatments. C) It ensures that participants are evenly distributed across treatment groups. D) It reduces the variability within treatment groups.

9.Which statistical technique is commonly used to analyze the results of a factorial experiment?
A) Analysis of Variance (ANOVA) B) Regression analysis C) Chi-square test D) Student's t-test

10 What is the purpose of randomization in experimental design?

A) To ensure that participants are evenly distributed across treatment groups B) To prevent participants from dropping out of the study C) To control for confounding variables D) To increase the likelihood of obtaining statistically significant results

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EAMCET Code: RBVW | PGECET Code: RBVW1

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FEEDBACK FORM DAY 4(session_1)

1.Name of the participant: V.Swetha

2.Name of the institute: rbvrr women college of pharmacy

3.Email address: Swethalk@gmail.com

4.How was the content delivered by the speaker..

- ☐ excellent
- ✓ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
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EAMCET Code: RBVW | PGECET Code: RBVW1

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FEEDBACK FORM DAY 4(session 2)

1 Name of the participant:.......G. Bhanuleri..........

2 Name of the institute:.. rbvrrwcp..........................
3 Email address:......83...1238@gmail.com.........
4 How was the content delivered by the speaker..
□ excellent ✓
□ very good
□ Good
5. How do you rate the session
□ excellent
□ very good ✓
□ good

6. Which phase of pharmaceutical development is most closely associated with the implementation of experimental design?

A) Pre-clinical development B) Clinical development C) Formulation development D) Manufacturing process development

7. What is the purpose of blocking in experimental design?

A) To ensure that each treatment group has the same number of participants B) To group similar experimental units together to reduce variability C) To randomize the assignment of treatments to participants D) To control for extraneous variables that cannot be controlled experimentally

8. Which type of experimental design involves each participant receiving all treatment conditions in a random order?

A) Crossover design B) Parallel-group design C) Factorial design D) Latin square design

9. What is the purpose of blinding in experimental design?

A) To prevent participants from dropping out of the study B) To ensure that the experiment is conducted in a double-blind manner C) To reduce the influence of biases on the outcome of the study D) To increase the likelihood of obtaining statistically significant results

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FEEDBACK FORM DAY 4(session 2)

1.Name of the participant: T. Swetha

2.Name of the institute: RBVRR women's college of pharmacy

3.Email address: Swetha14310@gmail.com

4.How was the content delivered by the speaker..

- ☐ excellent
- ☑ Very good
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5. How do you rate the session

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S.R. Nagar, Barkatpura, Hyderabad - 500027, Ph: 040-27662662
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TSAMCET Code: RBVW | PGECET Code: RBVW1

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FEEDBACK FORM DAY 5(session_1)

1.Name of the participant: Asma

2.Name of the institute: RBVRR WCOP

3.Email address: Asma.bhuvanagiri@gmail.com

4.How was the content delivered by the speaker..

- ☐ excellent
- ☑ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
- ☑ Very good
- ☐ good

6.Which statistical method is commonly used to analyze pharmacokinetic data in pharmaceutical development?

A) Analysis of Variance (ANOVA) B) Survival analysis C) Non-parametric tests D) Area under the curve (AUC) analysis

7.What is the purpose of performing a power analysis in pharmaceutical research?

A) To determine the optimal dosage of the drug B) To identify potential side effects of the drug C) To estimate the sample size needed to detect a significant treatment effect D) To analyze the variability in response to the drug among different individuals

8.Which of the following statistical tests is commonly used to compare means between two independent groups in pharmaceutical studies?

A) Student's t-test B) Chi-square test C) Analysis of Variance (ANOVA) D) Wilcoxon signed-rank test

9.What does the term "pharmacodynamics" refer to in pharmaceutical development?

A) The study of the absorption, distribution, metabolism, and excretion of drugs B) The study of drug interactions with biological systems and their effects C) The study of the biochemical mechanisms of drug action D) The study of adverse reactions to drugs

10 Which statistical measure is commonly used to express the association between two variables in pharmaceutical studies?

A) Odds ratio B) Hazard ratio C) Pearson correlation coefficient D) Relative risk

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EAMCET Code: RBVW | PGECET Code: RBVW1

Certificate course on by design of experiment in pharmaceutical development

FEEDBACK FORM DAY 5(session 1)

1.Name of the participant: Bhanusri

2.Name of the institute: RBVRR WCOP

3.Email address: Bhanusri2@gmail.com

4.How was the content delivered by the speaker..

- ☐ excellent
- ☐ very good
- ☑ Good

5. How do you rate the session

- ☐ excellent
- ☐ very good
- ☑ good

6.Which statistical method is commonly used to analyze pharmacokinetic data in pharmaceutical development?

A) Analysis of Variance (ANOVA) B) Survival analysis C) Non-parametric tests D) Area under the curve (AUC) analysis

7.What is the purpose of performing a power analysis in pharmaceutical research?

A) To determine the optimal dosage of the drug B) To identify potential side effects of the drug C) To estimate the sample size needed to detect a significant treatment effect D) To analyze the variability in response to the drug among different individuals

8.Which of the following statistical tests is commonly used to compare means between two independent groups in pharmaceutical studies?

A) Student's t-test B) Chi-square test C) Analysis of Variance (ANOVA) D) Wilcoxon signed-rank test

9.What does the term "pharmacodynamics" refer to in pharmaceutical development?

A) The study of the absorption, distribution, metabolism, and excretion of drugs B) The study of drug interactions with biological systems and their effects C) The study of the biochemical mechanisms of drug action D) The study of adverse reactions to drugs

10 Which statistical measure is commonly used to express the association between two variables in pharmaceutical studies?

A) Odds ratio B) Hazard ratio C) Pearson correlation coefficient D) Relative risk

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FEEDBACK FORM DAY 5(session 2)

1.Name of the participant: Gowthami

2.Name of the institute: RBVRRWCOP

3.Email address: Gowthami.e@gmail.com

4.How was the content delivered by the speaker..

- ☑ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ☑ excellent
- ☐ very good
- ☐ good

6.What is the purpose of conducting a post-hoc analysis in pharmaceutical research?

A) To determine whether the results are statistically significant B) To compare multiple treatment groups after detecting a significant omnibus test result C) To assess the validity of the experimental design D) To control for Type I errors in hypothesis testing

7.Which statistical measure is commonly used to express the association between two variables in pharmaceutical studies?

A) Odds ratio B) Hazard ratio C) Pearson correlation coefficient D) Relative risk

8.What is the primary purpose of conducting a sensitivity analysis in pharmaceutical research?
A) To assess the variability in response to the drug among different individuals B) To identify potential side effects of the drug C) To examine the robustness of study results to changes in assumptions or parameters D) To determine the optimal dosage of the drug

9.Which statistical technique is commonly used to analyze time-to-event data, such as survival or recurrence times, in pharmaceutical studies?

A) Analysis of Variance (ANOVA) B) Cox proportional hazards model C) Wilcoxon signed-rank test D) Friedman test

10.Which statistical technique is commonly used to account for confounding variables in observational studies in pharmaceutical research?

A) Stratification B) Regression analysis C) Matching D) Propensity score analysis

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FEEDBACK FORM DAY 5(session 2)

1.Name of the participant: Sulthana Rokhiya

2.Name of the institute: RBVRR WCOP

3.Email address: sulthanarokhiya@gmail.com

4.How was the content delivered by the speaker..

□ excellent
□ very good
□ Good

5. How do you rate the session

□ excellent
□ very good
□good

6.What is the purpose of conducting a post-hoc analysis in pharmaceutical research?

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3-6-343, Barkathpura, Hyderabad - 500027, Ph: 040-27563065
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FEEDBACK FORM DAY 6(session 1)

1 Name of the participant: Nikitha

2 Name of the institute: RBVRR WCOP

3 Email address: Nikitha@gmail.com

4 How was the content delivered by the speaker..

- ✓ Excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ✓ excellent
- ☐ very good
- ☐ good

6.What is the primary goal of employing Quality by Experimental Design in transdermal drug delivery system (TDDS) development?

A) To increase the production capacity of the TDDS B) To ensure compliance with regulatory requirements C) To optimize the formulation and manufacturing process D) To reduce the cost of production

7.Which statistical method is commonly used to optimize the formulation parameters in TDDS development?

A) Analysis of Variance (ANOVA) B) Regression analysis C) Chi-square test D) Student's t-test

8.What is the purpose of conducting a factorial design in TDDS development? A) To investigate potential drug interactions B) To compare the efficacy of different drug delivery systems C) To optimize multiple factors simultaneously D) To analyze the pharmacokinetics of the drug

9.Which of the following is NOT a key principle of Quality by Experimental Design in TDDS development?

A) Designing quality into the product B) Understanding and controlling the manufacturing process C) Conducting stability testing at different temperatures D) Employing statistical techniques to optimize parameters

10 What is the primary advantage of employing Quality by Experimental Design in TDDS development?

A) It ensures regulatory compliance B) It reduces the time and cost of development C) It eliminates the need for clinical trials D) It guarantees a high success rate in product launch

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FEEDBACK FORM DAY 6(session 1)

1.Name of the participant:.....Suvitha.....

2.Name of the institute:.....RBVRR WOP.....
3.Email address:.....suvithamanga@gmail.com.....
4.How was the content delivered by the speaker..
□ excellent
□ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
□good

6.What is the primary goal of employing Quality by Experimental Design in transdermal drug delivery system (TDDS) development?

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FEEDBACK FORM DAY 6(session 2)

1 Name of the participant: Uzma afreen

2 Name of the institute: rbvrwcop

3 Email address: –

4 How was the content delivered by the speaker..

- excellent
- very good
- Good

5 How do you rate the session

- excellent
- very good
- good

6.Which phase of TDDS development is most closely associated with the implementation of Quality by Experimental Design?

A) Pre-formulation studies B) Formulation development C) Preclinical studies D) Clinical trials

7.What is the purpose of establishing a Design Space in Quality by Experimental Design for TDDS?

A) To define the range of acceptable quality attributes for the product B) To identify critical process parameters that need to be controlled C) To specify the operating conditions under which the manufacturing process will consistently produce a quality product D) To conduct stability testing on the finished product

8.Which statistical method is commonly used to analyze the results of a factorial design in TDDS development?

A) Analysis of Variance (ANOVA) B) Chi-square test C) Regression analysis D) Student's t-test

9.What is the primary purpose of employing a crossover design in TDDS development?

A) To investigate the effects of different formulation parameters B) To eliminate carryover effects from previous treatments C) To assess the stability of the drug in different conditions D) To compare the efficacy of different drug delivery systems

10.Which phase of TDDS development is most closely associated with the implementation of Quality by Experimental Design?

A) Pre-formulation studies B) Formulation development C) Preclinical studies D) Clinical trials

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FEEDBACK FORM DAY 6(session 2)

1.Name of the participant:.....Pranaya Ragini

2.Name of the institute:.....RBVRRWCOP.....

3.Email address:.....

4.How was the content delivered by the speaker..

- ☑ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ☑ excellent
- ☐ very good
- ☐ good

6.Which phase of TDDS development is most closely associated with the implementation of Quality by Experimental Design?

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College Code: 1706

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 # 3-4-343, Barkathpura, Hyderabad - 500 027 (T.S), India

Office: +91 40-27563065, Mobile: +91 9848930555

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Recognized under Section 2(f) of the UGC Act 1956

EAMCET Code: RBVW | PGECET Code: RBVW1

www.rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com & rbvrrwcp2006@gmail.com

CERTIFICATE COURSE on

Regulatory affairs

27thAugust -1st September 2018

RBVRR Women' s College of Pharmacy

INAUGRAL SESSION

Dr. A. Krishna Sailaja

Prof. Head of dept of Pharmaceutics,

RBVRR Women's college of Pharmacy

PATRON

Prof. K. Muthyam Reddy

Hon. Secretary Cum Correspondent

RBVRR Women's College of Pharmacy

CONVENER

Prof. M. Sumakanth

Principal

RBVRR Women's College of Pharmacy

SPEAKERS	DATE & TIME
1. Dr. A. Krishna Sailaja Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	27thAugust 2018 & 28th August 2018
2. Raju Bhupathi Raja IP Attorney, Hyderabad	29th August 2018 & 30th August 2018
3. Dr. Priya Anish Mathews Scientist E, Project Monitoring & IPR Cell ARCA, Hyderabad	31st August 2018& 01st September 2018

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Value Added Course		
Course: Certificate course in Pharmaceutical Regulatory affairs		
Code: RA C001	**Credits:** 2	**Total No. of Hours** : 36

CERTIFICATE COURSE IN PHARMACEUTICAL REGULATORY AFFAIRS

Regulatory affairs is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, and by the companies responsible for the discovery, testing, manufacture and marketing of these products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare.

COURSE OBJECTIVES

The course is designed to teach all the regulations and rules of the industry. The curriculum of the certification is designed as a comparative analysis of Pharma regulatory systems of different nations integrated with concrete management tools of the supply chain like, Certification schemes, Regulatory compliance with government guidelines, product approval procedures etc. The study resources have been carefully designed to introduce the participant to various aspects and basics of industrial applications, its need, and benefits in assuring quality production.

SYLLABUS

Unit 1	**Overview of regulatory affairs**	**6 Hours**
Introduction to Global Regulatory Authorities in Pharmaceutical Industries, Drug Development Process, Regulatory Toxicology GMP and other good practices Introduction and the need for intellectual property right (IPR) - Kinds of Intellectual Property Rights: Patent, Copyright, Trade Mark, Design, Geographical Indication, Plant Varieties and Layout Design		

Unit 2	**Pharmaceutical Industry and IPR**	**8 Hours**

IPR in India : Genesis and development – IPR in abroad - Major International Instruments concerning Intellectual Property Rights: Paris Convention, 1883, the Berne Convention, 1886, the Universal Copyright Convention, 1952, the WIPO Convention, 1967,the Patent Co-operation Treaty, 1970, the TRIPS Agreement, 1994

Patents - Elements of Patentability: Novelty , Non Obviousness (Inventive Steps), Industrial Application - Non - Patentable Subject Matter - Registration Procedure, Rights and Duties of Patentee, Assignment and licence , Restoration of lapsed Patents, Surrender andRevocation of Patents, Infringement, Remedies & Penalties – Patent office and Appellate Board

Unit 3	**ICH and WHO guidelines**	**6 Hours**

A comprehensive training on the integrated implementation of Q8, Q9 and Q10 in pharmaceutical development and manufacturing, regulatory assessment, scale up, implementation into commercial manufacturing operations and GMP-inspection. A specific case study was used demonstrating opportunities when using the combination of Q8, Q9, Q10. A comprehensive training on regulatory aspects (regulatory expectations, dossier preparation, assessment and GMP-inspections) in addition to technical development and manufacturing details

Unit 4	**Dossier preparation in CTD format, eCTD submissions and drug registration**	**6 Hours**

It aims to introduce tools to assist the participants in formulating effective strategies in the development, compilation, and submission of US-compliant eCTDs Market authorization & electronic submission in major markets. Market authorization & submission in ROW markets (GCC, Africa), Dossier preparation in CTD Format, eCTD Submissions, Drug Registration in African Countries, Drug Registration in Gulf countries

Unit 5	**AYUSH Regulatory Affairs and Industry Based Case Studies**	**8 Hours**

Introduction to GMP and Traditional Systems of Medicine, importance of quality control and standardization of ayurvedic, siddha, unani and homeopathic systems of medicines of global acceptability. The source and quality of raw materials, storage, post-harvest handling and manufacturing process and stability studies,GMP requirements for AYUSH (International perspective)

Industry Based Case Studies

Regulatory Course Outcomes:

After completion of this course

1) After completion of the Programme, participant is expected to have in-depth knowledge and understanding of concept of generic drug and innovator, drug discovery and development , Regulatory strategy, approval process of all regulatory filings in various countries,
2) Students are thorough with the procedures and requirements and assist the participants in formulating effective strategies in the development, compilation, and submission of US- compliant eCTDs
3) This certification focuses on Good Manufacturing Practices (GMP), and to implement sensitive and practical analytical methods for standardization and quality control.
4) Participants may develop interdisciplinary knowledge and gain knowledge in filing process of IND, NDA and ANDA, IMPD, and Investigator Brochure (IB), DMF, US Hatch-Waxmn Act and code of federal regulations (CFR),
5) Participants will be exposed to global developments in the field of traditional systems based drugs; quality, safety and efficacy concern of the international community; and ways and methods to improve their manufacturing processes and techniques to assess quality of their products using modem techniques of analysis.

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Certificate course on RA

FEEDBACK FORM DAY 1

Name of the participant: Shwetha
Name of the institute: RBVRR WCOP
Email address: shwethabpharm@gmail.com

How was the content delivered by the speaker
Excellent
Very good
Good

How do you rate the session
Excellent
Very good
Good

Which type of intellectual property right protects inventions, providing exclusive rights for a limited period?
Patent
Copyright
Trade Mark
Design

Copyright primarily protects:
Inventions and discoveries
Literary, artistic, and musical works
Brand names and logos
Industrial designs

A trademark is a distinctive sign that identifies:
A product or service
A manufacturing process
A copyrighted work
An invention

Geographical Indication (GI) tags are primarily used to:

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Certificate course on IPR

FEEDBACK FORM DAY 5

1. Name of the participant: Gouthami Paul
2. Name of the institute: RBVRR WCP
3. Email address: Gauthmi.p@gmail.com
4. How was the content delivered by the speaker
   a) Excellent
   b) Very good
   c) Good
5. How do you rate the session
   a) Excellent
   b) Very good
   c) Good

6. What does Layout Design protection refer to?
a) Protection of the aesthetic elements of a website
b) Protection of the arrangement of integrated circuits
c) Protection of architectural designs
d) Protection of typography and font designs

7. What is the procedure for registration of Layout Designs?
a) Filing an application with the World Intellectual Property Organization (WIPO)
b) Filing an application with the International Bureau of Intellectual Property (IBIP)
c) Filing an application with the national intellectual property office
d) Filing an application with the United Nations Office for Outer Space Affairs (UNOOSA)

8. What is the effect of registration of Layout Designs?
a) Immediate protection worldwide
b) Exclusive rights to reproduce and distribute the layout design
c) Protection against any use of the layout design, regardless of intent
d) Protection for a limited time without renewal.

9. What is the term of protection for Layout Designs?
a) 10 years from the date of registration
b) 15 years from the date of registration
c) 20 years from the date of creation
d) Lifetime protection for the creator

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Certificate cuurse on RA

FEEDBACK FOR1¥I **DAY** 6

I. Name ut" the participant Nikitha
2 Namc of the institute RBVRR WOP
J. Fmail address Nikithagaula@gmail.com
4. I-l«•» as the content delivered hy ilie speaker..
Jexcellenl

n Good
5. How do you rate the se.ssion
be *cellent*
a ver *good*
a Good

6. What is the main difference between Geographical Indication (GI) and trademarks"
a) GJgrotects product names, wfiJe trademaks protect geographical locations
§} I indicates the origin of a product, while trademaks indicate the source of'guods or scn ices
c) GI protects inventions, while trademaks protect artistic creations
d) GI is only applicable to agricultural products, while trademaks apply to all industries

7. What is the procedtiie for register in _ ii Gco iilp liCNl Indicnti›n in India"
a) Filing an application with the Indian Patent Office
b) Filing an application with the Indian Trademark Registry
c) Filing an application with the Geographical Indications Registry
d) Filing an application with the Indian Copyright Office

8. What is the effect of registration of a Geographical Indication?
a) Ji.grants exclusive rights !• 's the t, cii aphital indi ati›n tu Ihc r<¿istruni
J‹ prevents anycnc fruin using the gct›gr•lphicaI illJicaliun. c\en if they w•rc using ii beli›r rcgisiratiun
c) It allO\\s for the gcugr‹iphicaI indication tu be uscd by anyunc without rcstri«tiuns
d) If FO\'id¢s protection fur an unlimitcd duration

9. What is the lcnn of protcclion for a registered Geographical Jndication in India'.'
a) 10 years from the date of' registration
) ! * j ears froM the date of registrar ion
! "' ?°"^! * *Drum* thc data u£ r¢gistraticn
d) lHdclânitc protection, *is long as the conditions are met

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Certificate course on RA

FEEDBACK FORM DAY 6

1..Name of the participant: Vishnuvardhan
2.Name of the institute: RBVRR Women's College of Pharmacy
3.Email address: vkpharmapal12@gmail.com
4.How was the content delivered by the speaker..
- ☐ excellent
- ☑ very good
- ☐ Good

5. How do you rate the session
- ☐ excellent
- ☑ very good
- ☐ Good

6.What is the main difference between Geographical Indication (GI) and trademarks?
a) GI protects product names, while trademarks protect geographical locations
b) GI indicates the origin of a product, while trademarks indicate the source of goods or services
c) GI protects inventions, while trademarks protect artistic creations
d) GI is only applicable to agricultural products, while trademarks apply to all industries

7.What is the procedure for registering a Geographical Indication in India?
a) Filing an application with the Indian Patent Office
b) Filing an application with the Indian Trademark Registry
c) Filing an application with the Geographical Indications Registry
d) Filing an application with the Indian Copyright Office

8.What is the effect of registration of a Geographical Indication?
a) It grants exclusive rights to use the geographical indication to the registrant
b) It prevents anyone from using the geographical indication, even if they were using it before registration
c) It allows for the geographical indication to be used by anyone without restrictions
d) It provides protection for an unlimited duration

9.What is the term of protection for a registered Geographical Indication in India?
a) 10 years from the date of registration
b) 15 years from the date of registration
c) 20 years from the date of registration
d) Indefinite protection, as long as the conditions are met

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3-4-343, Barkathpura, Hyderabad – 5000 027 (T.S), India

Office: +91 40-27563065, Mobile: +91 9848930555

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Recognized under section 2(f) of the UGC Act 1956

EAMCET Code: RBVW | PGECET Code: RBVW1

Two-week certificate course on "Advance Analytical Techniques"

INAUGRAL SESSION:

Mr. A. Venkata Rao

Manager, LC-MS Department,

Aurobindo pharma Ltd, Hyderabad.

FOR QUERIES:

Contact-

1. P. Kavya (8919889059)
2. 2. D.Sowjanya

Registration details:

Free Registration

Last date: 10th April, 2019

SCHEDULE

DAY	DATE	SPEAKER	TOPIC
DAY 1&2	19th & 20th April 2019	Mr. A Venkata Rao Manager, LC-MS Department, Aurobindo Pharma Ltd, Hyderabad.	LC-MS & GC-MS
Day 3&4	21st & 23rd April 2019	Mr. Y. Ramakoti Reddy, Technical Head, Avasya Labs, Hyderabad.	Mass Spectroscopy
DAY 5&6	24th &25th April 2019	Dr. K. Bhavya Sri, Associate Professor, Head, Dept of Pharma Analysis, RBVRR Womens College	Analytical Method Validation
Day 7&8	26th & 27th April 2019	Dr. G. Jithender Reddy, Senior Scientist, NMR Division, CSIR-IICT, Tarnaka, Hyderabad.	NMR Spectroscopic Techniques and their advancements
Day 9&10	28th & 30 April 2019	Industrial Visit;Mr. B. Sreekanth, AGM, HeadQuality Assurance, Caponex Labs Pvt Ltd, Hyderabad.	Qualification of Analytical instruments (NMR, MS, HPLC, UPLC & X-RAY Diffraction)

Day 1&2: Introduction to the programme (overview), welcoming principal mam and Speaker on to diase (giving bouquet) ,Inauguration, lightening of light, prayer song by students, principal mam addressing the gathering, giving introduction to speaker, at the end momento and vote of thanks.

Day 3&4: welcome to day 3 and 4 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & vote of thanks.

Day 5&6: welcome to day 5 and 6 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & vote of thanks.

Day 7&8: welcome to day 7 and 8 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & vote of thanks.

Day 9: welcome to day 9 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & vote of thanks.

Day 10: Industrial visit

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Barkatpura, Hyderabad- 500 027

TWO WEEK CERTIFICATE COURSE ON __ ADVANCED ANALYTICAL TECHNIQUES

FEEDBACK FORM DAY – 6&7 (SESSION – 1&2) :

1. Name of the participant and institute: Saipragna
2. Name of the institute: RBVRR women's College of pharmacy
3. Email id of the participant: saipallya@yahoo.co.in
4. How was the content delivered by the speaker? (Dr. G. Jithender Reddy)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. Which of the following are considered to be the lowest form of Electromagnetic Radiation
   a) IR Radiation
   b) Microwaves
   c) UV radiation
   d) Radio waves
7. What is used to cool the superconducting coils
   a) Hydrogen
   b) Ice
   c) Dry Ice
   d) Liquid Medium
8. NMR Spectroscopy indicates the chemical nature of _____ and Spatial positions of ____?
   a) Electrons; Protons
   b) Nuclei; Electrons
   c) Nuclei; Neighbouring Nuclei
   d) Neutrons; Electrons
9. When placed in magnetic field all random spins of the nuclei__
   a) Stop
   b) Reverse the direction
   c) Align with the magnetic field
   d) Rotate to 90° away from induced field
10. Was the session helpful and would you like to attend more sessions like this?
    - o Yes
    - o No
    - o Maybe

RBVRR WOMEN'S COLLEGE OF PHARMACY

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Barkatpura, Hyderabad- 500 027

TWO WEEK CERTIFICATE COURSE ON __ ADVANCED ANALYTICAL TECHNIQUES

FEEDBACK FORM DAY – 6&7 (SESSION – 1&2) :

1. Name of the participant and institute: Anjali
2. Name of the institute: RBVRR W COP
3. Email id of the participant: Anjali.devi@gmail.com
4. How was the content delivered by the speaker? (Dr. G. Jithender Reddy)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. Which of the following are considered to be the lowest form of Electromagnetic Radiation
   - a) IR Radiation
   - b) Microwaves
   - c) UV radiation
   - d) Radio waves
7. What is used to cool the superconducting coils
   - a) Hydrogen
   - b) Ice
   - c) Dry Ice
   - d) Liquid Medium
8. NMR Spectroscopy indicates the chemical nature of _____ and Spatial positions of ____?
   - a) Electrons; Protons
   - b) Nuclei; Electrons
   - c) Nuclei; Neighbouring Nuclei
   - d) Neutrons; Electrons
9. When placed in magnetic field all random spins of the nuclei__
   - a) Stop
   - b) Reverse the direction
   - c) Align with the magnetic field
   - d) Rotate to 90° away from induced field
10. Was the session helpful and would you like to attend more sessions like this?
    - o Yes
    - o No
    - o Maybe

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TWO WEEK CERTIFICATE COURSE ON __ ADVANCED ANALYTICAL TECHNIQUES

FEEDBACK FORM DAY – 1&2 (SESSION – 1&2) :

1. Name of the participant and institute: Nishath Fatima
2. Name of the institute: RBVRR WCOP
3. Email id of the participant: Nfatima@gmail.com
4. How was the content delivered by the speaker? (A. Venkatrao)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. Which of the following technique will be good for protein sequencing of Covid-19 virus
   a) GC-MS
   b) HPLC- MS
   c) ICP-MS
   d) All of the above
7. Write any three important interfaces in LC-MS
   a) mdecular Jet separator
   b) Permeation Interface
   c) open slit Interface
8. The Mass analyser is similar to which of the following optical spectrometer?
   a) Monochromator
   b) Detector
   c) Sample
   d) Source
9. Soft skills are required for?
   a) Communication
   b) Teamwork
   c) Flexibility and adaptability
   d) All of the above
10. Was the session helpful and would you like to attend more sessions like this?
    - o Yes
    - o No
    - o Maybe

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TWO WEEK CERTIFICATE COURSE ON __ ADVANCED ANALYTICAL TECHNIQUES

FEEDBACK FORM DAY – 1&2 (SESSION – 1&2) :

1. Name of the participant and institute: Khajija hasan.
2. Name of the institute: RBVRR WCOP
3. Email id of the participant: kadijahasan @ gmail.com
4. How was the content delivered by the speaker? (A.Venkatrao)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. Which of the following technique will be good for protein sequencing of Covid-19 virus
   a) GC-MS
   b) HPLC- MS
   c) ICP-MS
   d) All of the above
7. Write any three important interfaces in LC-MS
   a) Molecular separator
   b) Open slot interface
   c) Permeation interface.
8. The Mass analyser is similar to which of the following optical spectrometer?
   a) Monochromator
   b) Detector
   c) Sample
   d) Source
9. Soft skills are required for?
   a) Communication
   b) Teamwork
   c) Flexibility and adaptability
   d) All of the above
10. Was the session helpful and would you like to attend more sessions like this?
    - o Yes
    - o No
    - o Maybe

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TWO WEEK CERTIFICATE COURSE ON __ ADVANCED ANALYTICAL TECHNIQUES

FEEDBACK FORM DAY – 5&6 (SESSION – 1&2) :

1. Name of the participant and institute: Hindya Reddy
2. Name of the institute: RBVRR WCOP
3. Email id of the participant: Hindujareddy1@gmail.com
4. How was the content delivered by the speaker? (Dr.K.Bhavya Sree)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. The lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value?
   - a) Limit of detection
   - b) Accuracy
   - c) Limit of Quantitation
   - d) Specificity
7. Which is not one of the four major components in the overall validation process?
   - a) System suitability
   - b) Instrument qualification
   - c) Measurement validation
   - d) Software validation
8. Methods need to be validated, verified, and revalidated when the method is being transferred to another laboratory
   - a) True
   - b) False
9. How many parts make the overall validation process
   - a) 8
   - b) 4
   - c) 9
10. Was the session helpful and would you like to attend more sessions like this?
    - o Yes
    - o No
    - o Maybe

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TWO WEEK CERTIFICATE COURSE ON __ ADVANCED ANALYTICAL TECHNIQUES

FEEDBACK FORM DAY 5&6 (SESSION 1&2)

1. Name of the participant and institute: Yogi Murali
2. Name of the institute: RBVRWCOP
3. Email id of the participant: [illegible]@gmail.com
4. How was the content delivered by the speaker? (Dr.K.Bhavya Sree)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. The lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value?
   a) Limit of detection
   b) Accuracy
   c) Limit of Quantitation
   d) Specificity
7. Which is not one of the four major components in the overall validation process?
   a) System suitability
   b) Instrument qualification
   c) Measurement validation
   d) Software validation
8. Methods need to be validated, verified, and revalidated when the method is being transferred to another laboratory
   a) True
   b) False
9. How many parts make the overall validation process
   a) 8
   b) 4
   c) 9
10. Was the session helpful and would you like to attend more sessions like this?
    - o Yes
    - o No
    - o Maybe

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TWO WEEK CERTIFICATE COURSE ON __ ADVANCED ANALYTICAL TECHNIQUES

FEEDBACK FORM DAY 9&10 (SESSION 1&2)

1. Name of the participant and institute: Firdous
2. Name of the institute: RBVRR Women's College of Pharmacy
3. Email id of the participant: fahFirdous@gmail.com
4. How was the content delivered by the speaker? (Dr.B.Sreekanth)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
   - o
6. In HPLC detector linearity is checked by?

   Preparation & Analysis of set of several Independently prepared solutions.

7. Most commonly used GS-MS calibrant?

   perfluoro tri butylamine

8. Which of the following error occurs due to poor calibration of instrument?
   a. Random Error
   b. Gross Error
   c. Systematic Error
   d. Precision Error

9. What are the steps in qualification of NMR?

   IQ, PQ & OQ

10. Was the session helpful and would you like to attend more sessions like this?
    a. Yes
    b. No
    c. Maybe

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TWO WEEK CERTIFICATE COURSE ON __ ADVANCED ANALYTICAL TECHNIQUES

FEEDBACK FORM DAY – 9&10 (SESSION – 1&2) :

1. Name of the participant and institute : Sonia
2. Name of the institute: Rbvrr women College of Pharmacy
3. Email id of the participant : Soniathava@gmail.com
4. How was the content delivered by the speaker? (Dr.B.Sreekanth)
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
   - o
6. In HPLC detector linearity is checked by?

   preparation and analysis of set of serial independantly prepared solutions.

7. Most commonly used GS-MS calibrant?

   perfluro tributylamine

8. Which of the following error occurs due to poor calibration of instrument?
   a. Random Error
   b. Gross Error
   c. ✓ Systematic Error
   d. Precision Error

9. What are the steps in qualification of NMR?

   TQ, PQ & OQ

10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - b. No
    - c. Maybe

College Code: 1706

RBVRR WOMEN'S COLLEGE OF PHARMACY

 # 3-4-343, Barkathpura, Hyderabad - 500 027 (T.S), India

Office: +91 40-27563065, Mobile: +91 9848930555

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Recognized under Section 2(f) of the UGC Act 1956

EAMCET Code: RBVW | PGECET Code: RBVW1

www.rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com & rbvrrwcp2006@gmail.com

Value Added Course		
Course: Advance Analytical Techniques		
Code:AATCC001	**Credits:**2	**Total No.of Hours**:36

The aim of conducting this certificate course is to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing in Analytical and Bioanlytical laboratories

Objectives:-Objectives:- The Course Program in Advance Analytical Techniques is designed to provide participants with a comprehensive understanding of Analytical tools available and their advancements for the analysis of pharmaceutical products

SYLLABUS

Unit 1	**Spectroscopic Techniques and their Advancements**	**8 Hours**
NMR Spectroscopy:-Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double Resonance, Spin Spin and spin lattice relaxation phenomenon. 1D- NMR and 13CNMR. **Mass Spectroscopy:-**Principle, theory, instrumentation of mass spectrometry, different types of Ionization Techniques like Electron Impact, Chemical, Field, FAB and MALD, APCI, ESI, APPI, Mass fragmentation mechanism and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry.		
Unit 2	**Chromatographic Techniques and their Advancements**	**6 Hours**
Principle, Instrumentation and Pharmaceutical applications:- HPLC,UPLC, Nano LC, HILIC, GC, SFC		

Unit 3	Hyphenated Techniques	6 Hours
Principle, Instrumentation, Interfaces, Pharmaceutical applications:- LC-MS,GC-MS,ICP-MS, Tandem Mass systems		

Unit 4	X-ray Crystallography	4 Hours
Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction		

Unit 5	Qualification of Analytical Instruments	6 Hours
NMR, MS,HPLC,UPLC,X-ray diffraction		

Advance Analytical Techniques Course Outcomes:

After completion of this course

1) The students will get adequate knowledge on recent advancement and basics of NMR and MS.
2) Students will know the principle and advanced applications of Nano LC, UPLC and HILIC.
3) Students aware of different hyphenated techniques like ICP-MS, LC-MS GC-MS etc.
4) Students are permitted to know in detail about the X- ray crystallography methods and application.
5) Students are familiar with the methods used for calibration and validations of Instruments