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

(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

## CERTIFICATE COURSE ON

# QUALITY BY DESIGN IN FORMULATION DEVELOPMENT

RBVRR Womens college of pharmacy - SEMINAR HALL

Date: 07/04/2023 to 12/04/2023

**INAUGURAL SESSION:**
**Dr. A. Krishna Sailaja**
**Professor & Head, Dept. of Pharmaceutics,**
**RBVRR Women's College of Pharmacy**

**CONVENER**
**Prof. M. Sumakanth**
**Principal**
**RBVRR Women's College of pharmacy**

**Patron**
**Prof. K. Muthyam Reddy**
**Hon. Secretary cum correspondent**
**RBVRR Women's College of pharmacy**

| SPEAKERS | DATE & TIME |
| --- | --- |
| 1. Dr. A. Krishna Sailaja<br>Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy | 7TH April 2022 & 8TH April 2022 at 2.00 pm |
| 2. Dr. G. Uma Rani<br>Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy | 9TH April 2022 & 10TH April 2022 at 2.00 pm |
| 3. Dr. K.V. Ratnamala<br>Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy | 11TH April 2022 & 12TH April 2022 at 2.00 pm |

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|---|---|---|
| **Value Added Course** | | |
| **Course: Certificate course on quality by design in formulation development** | | |
| **Code:** QBD C002 | **Credits:** 2 | **Total No. of Hours** : 36 |

This certification will provide insight into the key principles of QbD covering quality risk management and formal experimental design. The certification is intended as continuing professional development (CPD) for professionals in the pharmaceutical industry, particularly in production, regulatory affairs and quality functions. The certification will offer an excellent introduction for those less familiar with QbD and provide new ideas on how to further implement the QbD concept in research. The case study based approach in certification programme is designed for working professionals in full time employment who want to update their knowledge and gain required skills and attitude in the area in order to become a certified GMP professional in the domain. This certification is also beneficial for professionals from different streams to help them intensify their knowledge. This is an advanced certification having rigorous case studies based methodology throughout the duration.

**Objectives:- Objectives:-** The Course Program in Quality by design in formulation development is designed to provide participants with a comprehensive understanding of the various aspects of QbD, such as Quallity test product performance, Critical quality attributes, Critical process parameters. QbD tools and studies include prior knowledge, risk assessment, mechanistic models, design of experiments (DoE) and data analysis, and process analytical technology (PAT). including patents, copyrights, trademarks, trade secrets, and Industrial Designs

**SYLLABUS**

| | | |
|---|---|---|
| **Unit 1** | **Overview of QbD** | **8 Hours** |

Introduction and the need for QbD in formulation development- objectives of QbD, Various components of QbD such as Quality test product performance, Identifcation of critical process parameters. Ctitical quality attributes, Critical manufacturing attributes in formulation development, risk assessment, risk management. The concept of Design of experiments, Factorial design in formulation optimization. How the DoE fit into the QbD concept.

| **Unit 2** | **Introduction to QTPP** | **8 Hours** |
|---|---|---|

Quality Target Product Profile that Identifies the Critical Quality Attributes of the Drug Product QTPP is a prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product. QTPP forms the basis of design for the development of the product. Considerations for inclusion in the QTPP could include the following Intended use in a clinical setting, route of administration, dosage form, and delivery system(s)Dosage strength(s),Container closure system, Therapeutic moiety release or delivery and attributes affecting pharmacokinetic characteristics (*e.g.*, dissolution and aerodynamic performance) appropriate to the drug product dosage form being developed, Drug product quality criteria (*e.g.*, sterility, purity, stability, and drug release) appropriate for the intended marketed product

| **Unit 3** | QbD Methodology and its Implementation | **7 Hours** |
|---|---|---|

Elements of QbD, Importance of Critical Process parameters in formulation optimization, Critical Material attributes and its significance in optimization process. Selection of Critical quality attributes in various dosage forms. Regulatory and Industry views on QbD, Scientifically based examples of application of QbD.

| **Unit 4** | ICH Q8 Guidelines and factorial design | **7 Hours** |
|---|---|---|

Introduction to ICHQ8 Guidelines, risk management and risk analysis.Concept of optimization, optimization parameters, Screening techniques and optimization techniques. Factorial design, 2 level and 3 level factorial design, Formulation of various dosage forms such as microemulsions, Nanoparticles by applying factorial design. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Population modeling sensitivity analyis

| **Unit 5** | Controlling strategy and product life cycle management | **6 Hours** |
|---|---|---|

**Design**

Introduction to ICH Q10 , A control strategy for input material controls, process controls and monitoring, design space around individual or multiple unit operations, and/or final product specifications which ensure consistent quality. Testing of finished drug products for quality by assessing their specifications. A QbD based control strategy for various dosage forms such as tablets, capsules and novel drug delivery systems

**QbD Course Outcomes:**

**After completion of this course**

1) The students will get adequate knowledge on concepts and applications of QbD, objectives, the QbD approach in formulation development
2) Students are thorough with the implementation of QbD in formulation development, method development, and manufacturing
3) Students Gain knowledge regarding identification of Critical Process parameters, Critical quality attributes and critical material attributes.
4) Participants may develop knowledge regarding risk identification, risk analysis and risk reduction
5) Participants develop knowledge on QbD based control strategy for various dosage forms as tablets, capsules and novel drug delivery systems

**Certificate course - QBD** LIST OF PARTICIPANTS(2022-23):

| S.NO | NAME OF THE PARTICIPANT |
|---|---|
| 1 | KEERTHANA G |
| 2 | CHENCHARAM TULASI |
| 3 | L ARCHITHA |
| 4 | NIDA MIRZA BAIG |
| 5 | AKULA VAISHNAVI |
| 6 | CHAVAN DIVYA |
| 7 | GONE MANUSHA |
| 8 | JIMKALA PRAVALLIKA |
| 9 | KALALI GURUGEETHA |
| 10 | RAMDENI KAVYA |
| 11 | TAILORS KEERTHANA |
| 12 | TATHODE BHAGYASRI |
| 13 | THANDRA AMBIKA |
| 14 | DESHMUKH SHREYA |
| 15 | G.HARSHITHA |
| 16 | GANGULA SRILATHA |
| 17 | HADIA ANJUM |
| 18 | KARRAHE RAJINI |
| 19 | KAVALI LAVANYA |
| 20 | MASIGIRI ARCHANA |
| 21 | NAZMEEN KAUSAR |
| 22 | PERIKALA VASANTHI |
| 23 | RAVULA SAI NANDINI |
| 24 | UBALE SAMIKSHA |

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| 25 | GHOOLI INDU |
| 26 | PENTELA MOHANA LAKSHMI |
| 27 | RAMSHA MEHDIYA |
| 28 | RAPOTHULA ROOPA RANI |
| 29 | SAMREEN TABASSUM HUSSAIN |
| 30 | SANA FATIMA |
| 31 | SHAIK INSHA AHMED |
| 32 | SUMAIYA FIRDOUS |
| 33 | TALLOJU TEJASRI |
| 34 | ZEBA FATIMA |
| 35 | AMTUL RAHMAN |
| | |
| | |

**RBVRR WOMENS COLLEGE OF PHARMACY**

**Attendance sheet of QBD**

| S.NO | NAME OF THE PARTICIPANT | Name of the college | 5/6/23 | 6/6/23 | 7/6/23 | 8/6/23 | 9/6/23 | 10/6/23 |
|---|---|---|---|---|---|---|---|---|
| 1 | KEERTHANA G | | | | | | | |
| 2 | CHENCHARAM TULASI | RBVRR WCP. | Tulasi | Tulasi | Tulasi | Tulasi | Tulasi | Tulasi |
| 3 | L ARCHITHA | RBVRR WCP | Archiths | Archiths | Archiths | Archiths | Archiths | Archiths |
| 4 | NIDA MIRZA BAIG | RBVRR WCP. | Nida | Nida | Nida | Nida | Nida | Nida |
| 5 | AKULA VAISHNAVI | " | Vaish | Vaish | Vaish | Vaish | Vaish | Vaish |
| 6 | CHAVAN DIVYA | RBVRRWCP | Divya | Divya | Divya | Divya | Divya | Divya |
| 7 | GONE MANUSHA | RBVRR-WCP | Manu | Manu | Manu | Manu | Manu | Manu |
| 8 | JIMKALA PRAVALLIKA | " | Prav | Prav | Prav | Prav | Prav | Prav |
| 9 | KALALI GURUGEETHA | RBVRR-WCP | K.guru | K.guru | K.guru | K.guru | K.guru | K.guru |
| 10 | RAMDENI KAVYA | " | Kavya | Kavya | Kavya | Kavya | Kavya | Kavya |
| 11 | TAILORS KEERTHANA | RBVRRWCP | | | | | | |
| 12 | TATHODE BHAGYASRI | " | Bhagya | Bhagya | Bhagya | Bhagya | Bhagya | Bhagya |
| 13 | THANDRA AMBIKA | RBVRRWCP | Ambika | Ambika | Ambika | Ambika | Ambika | Ambika |
| 14 | DESHMUKH SHREYA | " | Shr | Shr | Shr | Shr | Shr | Shr |
| 15 | G.HARSHITHA | RBVRR-WCP | drshitha | drshitha | drshitha | drshitha | drshitha | drshitha |
| 16 | GANGULA SRILATHA | " | Sri | Sri | Sri | Sri | Sri | Sri |
| 17 | HADIA ANJUM | RBVRRWCP. | Anj | Anj | Anj | Anj | Anj | Anj |
| 18 | KARRAHE RAJINI | RBVRRWCP | Raj | Raj | Raj | Raj | Raj | Raj |
| 19 | KAVALI LAVANYA | " | Lav | Lav | Lav | Lav | Lav | Lav |
| 20 | MASIGIRI ARCHANA | RBVRRWCP | Archana | Archana | Archana | Archana | Archana | Archana |
| 21 | NAZMEEN KAUSAR | " | Naz11 | Naz11 | Naz11 | Naz11 | Naz11 | Naz11 |
| 22 | PERIKALA VASANTHI | RBVRR-WCP. | P.V | P.V | P.V | P.V | P.V | P.V |
| 23 | RAVULA SAI NANDINI | " | Nandini | Nandini | Nandini | Nandini | Nandini | Nandini |
| 24 | UBALE SAMIKSHA | RBVRR-WCP. | Samiksh | Samiksh | Samiksh | Samiksh | Samiksh | Samiksh |
| 25 | GHOOLI INDU | " | Indu | Indu | Indu | Indu | Indu | Indu |
| 26 | PENTELA MOHANA LAKSHMI | RBVRR-WCP | lakshmi | lakshmi | lakshmi | lakshmi | lakshmi | lakshmi |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 27 | RAMSHA MEHDIYA | RBVRR WCP | Ramsha | Ramsha | Ramsha | Ramsha | Ramsha | Ramsha |
| 28 | RAPOTHULA ROOPA RANI | " | RR. Rani | RR. Rani | RR. Rani | RR. Rani | RR. Rani | RR. Rani |
| 29 | SAMREEN TABASSUM HUSSAIN | RBVRRWCP | Samr | Samr | Samr | Samr | Samr | Samr |
| 30 | SANA FATIMA | " | asf | asf | asf | asf | asf | asf |
| 31 | SHAIK INSHA AHMED | RBVRR-WCP | Insha | Insha | Insha | Insha | Insha | Insha. |
| 32 | SUMAIYA FIRDOUS | " | Sum | Sum | Sum | Sum | Sum | Sum |
| 33 | TALLOJU TEJASRI | " | Tej | Tej | Tej | Tej | Tej | Tej |
| 34 | ZEBA FATIMA | " | Zeba | Zeba | Zeba | Zeba | Zeba | Zeba |
| 35 | AMTUL RAHMAN | " | | | | | | |
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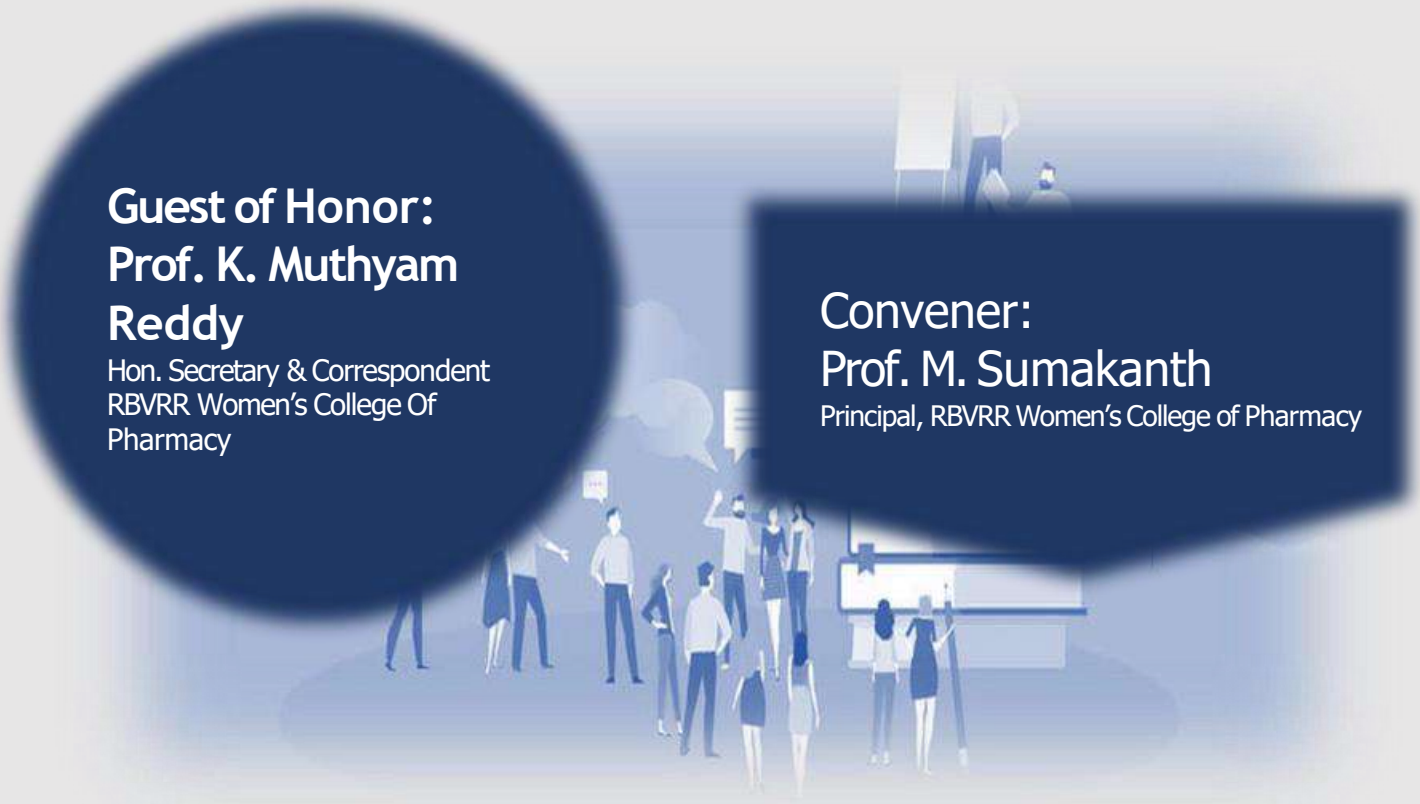
www.rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com & rbvrrwcp2006@gmail.com

Invites you to the
Certificate Course on

# ''PROFESSIONAL DEVELOPMENT''

**2nd July 2022, 10:30 AM**



**Guest of Honor:**
**Prof. K. Muthyam Reddy**
Hon. Secretary & Correspondent
RBVRR Women's College Of Pharmacy

Convener:
Prof. M. Sumakanth
Principal, RBVRR Women's College of Pharmacy

# Programme Schedule

| DATE | SPEAKER |
|---|---|
| 2nd & 4thJul 2022 | **Prof. Purushottam Reddy**<br>Retd. Professor Osmania University |
| 5th & 6th Jul 2022 | **Ramakrishna Sistla**<br>Senior Scientist IICT |
| 7th& 8th Jul 2022 | **Prof. M. Sumakanth**<br>Principal<br>RBVRR Women's College Of Pharmacy |
| 9th Jul 2022 | **P. Anuradha Reddy** |

| Value Added Course | | |
|---|---|---|
| Course: PROFESSIONAL DEVELOPMENT | | |
| **Code:** PDC005 | **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.

SYLLABUS

| 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. Measureme 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 sa 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 a 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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EAMCET Code: RBVW | PGECET Code: RBVW1

Certificate course - Professional Development (2022-23)

**LIST OF PARTICIPANTS**

| S. No | Name of the Students |
|---|---|
| 1 | ADDAGULLA RASHMITHA |
| 2 | ADEEBA MAHEK |
| 3 | ADEPU SRAVANI |
| 4 | ALUGUBELLI AKSHITHA |
| 5 | ANKITA VENKATESH SURA |
| 6 | ASIA |
| 7 | AZMEERA ESHWARI |
| 8 | BANOTHU DEEVENA |
| 9 | BANTU KEERTHANA |
| 10 | BEJJANKI HEMA |
| 11 | BHANALA AKANKSHA |
| 12 | BHEEMAGANI ASHWITHA |
| 13 | BHUTHKURE AKHILA |
| 14 | BURRA DEVAHARSHINI |
| 15 | BYATHOLI PRAVALIKA |
| 16 | CH DEEPTHI |
| 17 | CH SRINIJA |
| 18 | CHANDRAGIRI SUSHMITHA |
| 19 | CHAVAN RENUKA |
| 20 | CHERUKU UMA |
| 21 | CHITHAKARI AKSHAYA |
| 22 | D.KAVERI |
| 23 | DARA VIJAYA LAXMI |

| | |
|---|---|
| 24 | DASARAM ABHINAYA |
| 25 | DONTHI<br>JESHWITHA |
| 26 | DUBBAKA MANASA |
| 27 | E MOUNIKA |
| 28 | ENGALA ASHWITHA |
| 29 | G SAI PRIYA REDDY |
| 30 | GABBITA PRAGNYA |
| 31 | GILLELA SATHVIKA |
| 32 | GURIJALA SPANDANA |
| 33 | HAFSA ABDUL RAHMAN |
| 34 | INDRAKANTI NAVYA |
| 35 | JATOTHU ANITHA |
| 36 | JUKKALWAR ASHWINI |
| 37 | KONKI INDIRA<br>PRIYA DARSHINI |
| 38 | K VARSHITHA |
| 39 | KAILA DEEPIKA |
| 40 | KANDURI VARSHA |
| 41 | KATAKAM SAMPRATHI |
| 42 | KATROTH AKHILA |
| 43 | KHAULA ABDUL RAHMAN |
| 44 | KOLAGANI KALPANA |
| 45 | KONDA SRAVYA |
| 46 | KORAA ANJALI |
| 47 | KOTAKONDA KAVYA SREE |
| 48 | KRISHNAVENI MUKKIDI |
| 49 | KUMMARI SANDHYA |
| 50 | LAKAVATH SHIRISHA |
| 51 | LAKKAPATHRI MANASA |

**RBVRR WOMEN'S COLLEGE OF PHARMACY**

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**Approved by AICTE and PCI, Affiliated to Osmania University**

EAMCET code: **RBVW** | PGECET code: RBVWI

**Name of the course:** Professional Development **Course code:** PDC005 **Date:** 2/07/22.

| S. No | Name of the Students | DAY-1 FN | DAY-1 AN | DAY-2 FN | DAY-2 AN | DAY-3 FN | DAY-3 AN | DAY-4 FN | DAY-4 AN | DAY-5 FN | DAY-5 AN | DAY-6 FN | DAY-6 AN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ADDAGULLA RASHMITHA | | | | | | | | | | | | |
| 2 | ADEEBA MAHEK | | | | | | | | | | | | |
| 3 | ADEPU SRAVANI | | | | | | | | | | | | |
| 4 | ALUGUBELLI AKSHITHA | | | | | | | | | | | | |
| 5 | ANKITA VENKATESH SURA | | | | | | | | | | | | |
| 6 | ASIA | | | | | | | | | | | | |
| 7 | AZMEERA ESHWARI | | | | | | | | | | | | |
| 8 | BANOTHU DEEVENA | | | | | | | | | | | | |
| 9 | BANTU KEERTHANA | | | | | | | | | | | | |
| 10 | BEJJANKI HEMA | | | | | | | | | | | | |
| 11 | BHANALA AKANKSHA | | | | | | | | | | | | |
| 12 | BHEEMAGANI ASHWITHA | | | | | | | | | | | | |
| 13 | BHUTHKURE AKHILA | | | | | | | | | | | | |
| 14 | BURRA DEVAHARSHINI | | | | | | | | | | | | |
| 15 | BYATHOLI PRAVALIKA | | | | | | | | | | | | |
| 16 | CH DEEPTHI | | | | | | | | | | | | |
| 17 | CH SRINIJA | | | | | | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 18 | CHANDRAGIRI SUSHMITHA | | | | | | | | | | | | |
| 19 | CHAVAN RENUKA | | | | | | | | | | | | |
| 20 | CHERUKU UMA | | | | | | | | | | | | |
| 21 | CHITHAKARI AKSHAYA | | | | | | | | | | | | |
| 22 | D.KAVERI | | | | | | | | | | | | |
| 23 | DARA VIJAYA LAXMI | | | | | | | | | | | | |
| 24 | DASARAM ABHINAYA | | | | | | | | | | | | |
| 25 | DONTHI JESHWITHA | | | | | | | | | | | | |
| 26 | DUBBAKA MANASA | | | | | | | | | | | | |
| 27 | E MOUNIKA | | | | | | | | | | | | |
| 28 | ENGALA ASHWITHA | | | | | | | | | | | | |
| 29 | G SAI PRIYA REDDY | | | | | | | | | | | | |
| 30 | GABBITA PRAGNYA | | | | | | | | | | | | |
| 31 | GILLELA SATHVIKA | | | | | | | | | | | | |
| 32 | GURIJALA SPANDANA | | | | | | | | | | | | |
| 33 | HAFSA ABDUL RAHMAN | | | | | | | | | | | | |
| 34 | INDRAKANTI NAVYA | | | | | | | | | | | | |
| 35 | JATOTHU ANITHA | | | | | | | | | | | | |
| 36 | JUKKALWAR ASHWINI | | | | | | | | | | | | |
| 37 | KONKI INDIRA PRIYA DARSHINI | | | | | | | | | | | | |
| 38 | K VARSHITHA | | | | | | | | | | | | |
| 39 | KAILA DEEPIKA | | | | | | | | | | | | |
| 40 | KANDURI VARSHA | | | | | | | | | | | | |
| 41 | KATAKAM SAMPRATHI | | | | | | | | | | | | |
| 42 | KATROTH AKHILA | | | | | | | | | | | | |
| 43 | KHAULA ABDUL RAHMAN | | | | | | | | | | | | |

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| 44 | KOLAGANI KALPANA | | | | | | | | | | | | | |
| 45 | KONDA SRAVYA | | | | | | | | | | | | | |
| 46 | KORAA ANJALI | | | | | | | | | | | | | |
| 47 | KOTAKONDA KAVYA SREE | | | | | | | | | | | | | |
| 48 | KRISHNAVENI MUKKIDI | | | | | | | | | | | | | |
| 49 | KUMMARI SANDHYA | | | | | | | | | | | | | |
| 50 | LAKAVATH SHIRISHA | | | | | | | | | | | | | |
| 51 | LAKKAPATHRI MANASA | | | | | | | | | | | | | |

College Code: 1706

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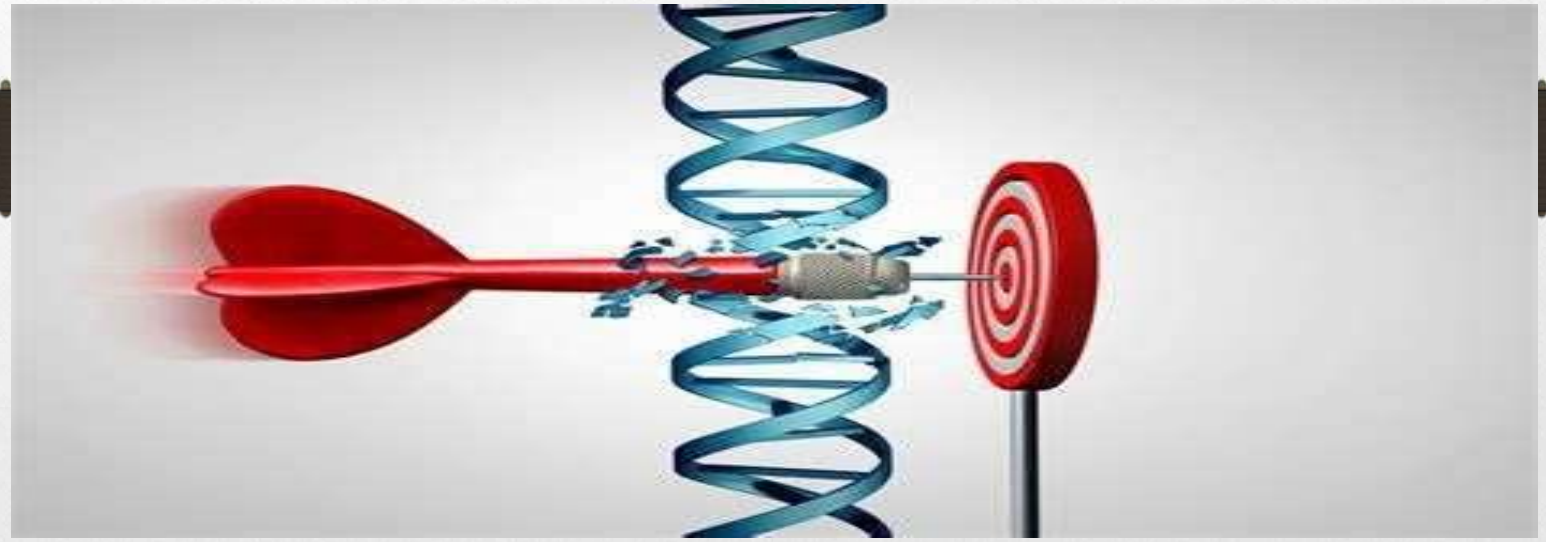
EAMCET Code: RBVW | PGECET Code: RBVW1

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

# CERTIFICATE COURSE on

# TARGETED DRUG DELIVERY SYSTEM



**Date and Time:**
**6TH - 11TH JUNE ,2022**
**RBVRR Womens college of pharmacy - SEMINAR HALL**

**INAUGURAL SESSION:**
**Dr. A. Krishna Shailaja**
**Prof. Head of Dept of Pharmaceutics, RBVRR Womens 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<br>Professor & Head, Dept. of Pharmaceutics,<br>RBVRR Women's College of Pharmacy | 6TH June 2022 & 7th June 2022 at 2.00 pm |
| 2. Dr. K.V. Ratnamala<br>Associate Professor, Dept. of Pharmaceutics,<br>RBVRR Women's College of Pharmacy | 8TH June 2022 & 9th June 2022 at 2.00 pm |
| 3. Dr. Shyam Lal M<br>Associate Professor,<br>Department of Animal Biology,<br>School of Life Sciences,<br>University of Hyderabad | 10TH June 2022 & 11th June 2022 at 2.00 pm |

| Value Added Course | | |
|---|---|---|
| **Course: Certificate course on targeted drug delivery systems** | | |
| **Code:** TDS C001 | **Credits:** 2 | **Total No. of Hours** : 36 |

This certification will provide insight into the various approaches for development of novel drug delivery systems. It helps the scientist to understand the criteria for selection of drugs and polymers for the development of delivering system. It explains about the formulation and evaluation of Novel drug delivery systems

**Objectives:- Objectives:-** The Course Program in on targeted drug delivery systems is designed to provide participants with a comprehensive understanding of the targeted drug delivery systems such as nanoparticles, micropartcles. This course explains about recent advancements in Transdermal drug delivery systems such as iontophoresis and sonophoresis techniques. It helps the participants to have in depth knowledge on different types of vesicular drug delivery systems

**SYLLABUS**

| **Unit 1** | **Overview of targeted drug delivery** | **8 Hours** |
|---|---|---|
| Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. | | |

| **Unit 2** | **Particulate drug delivery systems** | **8 Hours** |
|---|---|---|
| Introduction to nanoparticles, Different techniques for the preparation of nanoparticles, Evaluation of nanoparticles, Various applications of nanoparticles,<br>Introduction to microspheres and Microcapsules. Advantages and limitations of microspheres and microcapsules. Various techniques for the formulation and evaluation of microspheres,<br>Microballons- A novel carrier for drug delivery | | |

| |
|---|
| Different techniques for the fotmulation of microcapsules, Evaluation and applications of microcapsules |

| **Unit 3** | **Vesicular drug delivery systems** | **8 Hours** |
|---|---|---|
| Introduction to vesicular drug delivery systems. Classification and general applications of vesicular drug delivery systems. Introduction to liposomes. Different techniques, evaluation procedures for the formulation of liposomes. Niosomes, classification and evaluation<br>Formulation and evaluation of ethosomes, transferosomes, invasomes, electrosomes, aquasomes, cubosomes. Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.Recent advancements in Transdermal drug delivery systems | | |

| **Unit 4** | **Protein and peptide drug delivery** | **6 Hours** |
|---|---|---|
| Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. | | |

| **Unit 5** | **Gene therapy** | **6 Hours** |
|---|---|---|
| Introduction to gene therapy. Exvivo and invivo gene therapy. Potential target diseases for gene therapy .Gene expression systems. Vectors for gene delivery. Virosomes a novel carrier Liposomal gene delivery systems. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. | | |

**TDDS Course Outcomes:**

**After completion of this course**

1) The students will get adequate knowledge on concepts and applications of nanoparticle drug delivery systems in brain and cancer targeting
2) Students are thorough with the procedures and applications of different vesicular drug delivery systems such as liposomes and niosomes
3) Students Gain insights into the gene delivery procedures and potential targets for gene delivery
4) Participants may develop interdisciplinary knowledge by understating the concept of protein and peptde drug delivery systems
5) Participants develop knowledge on recent advancements in Transdermal drug delivery systems and permeation enhancers applications

**Certificate course -TDDS(20-21)**

**LIST OF PARTICIPANTS**

| S.NO | NAME OF THE PARTICIPANT |
|---|---|
| 1 | Agaldeeti Ishwarya |
| 2 | Bashair Ayni |
| 3 | Boraa Meghana |
| 4 | D Kanaka Durga |
| 5 | John Chelsea Ruth |
| 6 | Jyoti |
| 7 | Munazzah Tehreem |
| 8 | Neharika Bommaganti |
| 9 | Pulijala Uma |
| 10 | Saba Begum |
| 11 | V.Pooja Ramesh |
| 12 | Yanamandra Lalithalaharika |

**RBVRR WOMENS COLLEGE OF PHARMACY**

**Attendance sheet of TDDS**

| S.NO | NAME OF THE PARTICIPANT | Name of the college | 6/6/22 | 7/6/22 | 8/6/22 | 9/6/22 | 10/6/22 | 11/6/22 |
|---|---|---|---|---|---|---|---|---|
| 1 | Agaldeeti Ishwarya | RBVRR WCP | | | | | | |
| 2 | Bashair Ayni | RBVRR WCP | | | | | | |
| 3 | Boraa Meghana | RBVRR WCP | | | | | | |
| 4 | D Kanaka Durga | RBVRR WCP | | | | | | |
| 5 | John Chelsea Ruth | RBVRR WCP | | | | | | |
| 6 | Jyoti | RBVRR WCP | | | | | | |
| 7 | Munazzah Tehreem | RBVRR WCP | | | | | | |
| 8 | Neharika Bommaganti | RBVRR WCP | | | | | | |
| 9 | Pulijala Uma | RBVRR WCP | | | | | | |
| 10 | Saba Begum | RBVRR WCP | | | | | | |
| 11 | V.Pooja Ramesh | RBVRR WCP | | | | | | |
| 12 | Yanamandra Lalithalaharika | RBVRR WCP | | | | | | |

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

(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

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# Certificate Course on

# REGULATORY AFFAIRS


7TH-12TH March 2022

RBVRR Womens college of pharmacy - SEMINAR HALL

INAUGURAL SESSION:

Dr. A. Krishna Shailaja

Prof. Head of Dept of Pharmaceutics,
RBVRR Womens 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<br>Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy | 7TH March 2022 & 8th March 2022 at 2.00 pm |
| 2. Raju Bhupathi Raja<br>IP Attorney, Hyderabad | 9TH March 2022 & 10th March 2022 at 2.00 pm |
| 3. Dr. Priya Anish Mathews<br>Scientist E, Project Monitoring & IPR Cell ARCA, Hyderabad | 11TH March 2022 & 12th March 2022 at 2.00 pm |

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EAMCET Code: RBVW | PGECET Code: RBVW1

| Value Added Course | | |
|---|---|---|
| **Course: Certificate course in Pharmaceutical Regulatory affairs** | | |
| **Code:** PRA 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<br>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)<br>**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.

**Certificate course -** REGULATORY AFFAIRS

LIST OF PARTICIPANTS:

| S.NO | NAME OF THE PARTICIPANT |
|---|---|
| 1 | Amand Alekhya |
| 2 | Buyani Tejasree |
| 3 | D T Krishna Sinjitha |
| 4 | Ganparaju Vaishnavi |
| 5 | Lakkakula Sravanthi |
| 6 | Mandhra Monalisa |
| 7 | Moguloori Sai Sowmya |
| 8 | Mubasshera Maham |
| 9 | Narigandla Vasavi |
| 10 | Narkuda Manisha |
| 11 | Palle Annie Jerusha |
| 12 | Pappireddy Lahari |
| 13 | Syeda Ruhina Anjum |
| 14 | Thoudaboina Meghana |

**RBVRR WOMENS COLLEGE OF PHARMACY**

**Attendance sheet of Regulatory affairs**

| S.NO | ME OF THE PARTICIPA | Name of the college | 7/3/22 | 8/3/23 | 9/3/22 | 10/3/22 | 11/3/22 | 12/3/22 |
|---|---|---|---|---|---|---|---|---|
| 1 | Amand Alekhya | RBVRR WCP | Alekhya | Alekhya | Alekhya | Alekhya | Alekhya | Alekhya |
| 2 | Buyani Tejasree | " | Teja | Teja | Teja | Teja | Teja | Teja |
| 3 | D T Krishna Sinjitha | " | Krisha | Krisha | Krishna | Krishna | Krishna | Krishna |
| 4 | Ganparaju Vaishnavi | " | Vaishu | Vaishu | Vaishu | Vaishu | Vaishu | Vaishu |
| 5 | Lakkakula Sravanthi | " | Mona | Mona | Mona | Mona | Mona | Mona |
| 6 | Mandhra Monalisa | " | Mona | Mona | Mona | mona | Mona | Mona |
| 7 | Moguloori Sai Sowmya | " | Sai | Sai | Sai | Sai | Sai | Sai |
| 8 | Mubasshera Maham | " | Maha | Maha | Maha | Maham | Maha | Maham |
| 9 | Narigandla Vasavi | " | Vasavi | Vasavi | Vasavi | Vasavi | Vasavi | Vasavi |
| 10 | Narkuda Manisha | " | Mana | Mana | Mana | Mana | Mana | Mana |
| 11 | Palle Annie Jerusha | " | Annie | Annie | Annie | Annie | Annie | Annie |
| 12 | Pappireddy Lahari | " | Lahari | Lahari | Lahari | Lahari | Lahari | Lahari |
| 13 | Syeda Ruhina Anjum | " | Anjum | Anjum | Anjum | Anjum | Anjum | Anjum |
| 14 | Thoudaboina Meghana | " | Megha | Megha | Megha | Megha | Megha | Megha |

College Code: 1706

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# CERTIFICATE COURSE ON INDIAN TRADITIONAL MEDICINE

**Date:**
3rd Oct,2020 – 10th Oct, 2020
**Venu:**
Seminar Hall
RBVRR Women's College of Pharmacy

INAUGURAL SESSION:

**Dr.Sudha Parimala**,
Associate Professor,
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

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EAMCET Code: RBVW | PGECET Code: RBVW1

| VALUE ADDED COURSE |
|---|
| COURSE: INDIAN TRADITIONAL MEDICINE |
| Duration: From 03-10-2020 To 10-10-2020 Credits: 02 Total no. of hours: 36 |
| Lectures: 10:30 to 12:30 Workshops: 1:00 to 5:00 |

This course strategy will prove to be effective in creating awareness for benefits of Indian traditional medicinal and aromatic plants, increasing conservation and employment as well as entrepreneurial opportunities. Various Indian traditional medicinal plants are in demand in global market, yet many farmers/tribals/learners hardly know about: how to cultivate and harvest or where to find market? This course intervention is focused on reclaiming sustainability in Indian traditional medicinal and aromatic plants through educating learners with scientific know-hows, guidelines, quality policies, processing and developing a viable value addition and sustainable product.

## Objectives:

To aware learners (student, faculty, professional) about the rich Indian traditional knowledge of medicinal and aromatic plants, their protection, regulations, quality control and market.

- To clear myths and propose scientific evidences of traditional medicinal and aromatic plants benefits.
- To aware learners about cultivation, conservation, value addition and socioeconomic development through the knowledge of Indian Traditional Medicinal and Aromatic plants
- To aware learners (especially urban) to identify few important Traditional Medicinal and Aromatic plants
- To aware learners about Entrepreneurship and Start-up opportunities based on market for Indian Traditional Medicinal and Aromatic plants.

## Eligibility:

Anyone who is having interest in Medicinal and Aromatic Plants can enrol this course. Student, professionals, faculty from pharmacy, alternative medicines, life sciences, biotechnology, agriculture, natural chemistry and food technology.

## Course layout:

| **Lecture-1** | **2 HOURS** |
|---|---|
| **Introduction to Ayurveda, Siddha, Unani, Homeopathy & Sowa-Rigpa Systems and Traditional Formulations** | |
| **Speaker:** Dr. Chidamabara Murthy, HOD, Ramaiah College Of Pharmacy Bengaluru | |
| Traditional medicine (also known as indigenous medicine or folk medicine) comprises medical aspects of traditional knowledge that developed over generations within the folk beliefs of various societies, including indigenous peoples, before the era of modern medicine. The World Health Organization (WHO) defines traditional medicine as "the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement and treatment of physical and mental illness". Traditional medicine is often contrasted with scientific medicine. | |
| **Workshop**: Dr. Sudha Parimala | **4 HOURS** |
| **Extraction** Different methods of extraction like maceration, percolation and Soxhlet extraction of crude drugs, Difference between soft & dry extracts. | |

| **Lecture -II** | **2 HOURS** |
|---|---|
| **Important Medicinal Plants mentioned in ancient texts** | |
| **Speaker**: Dr. Mruthyunjaya Kenganoora, HOD, Deparment of Pharmacognosy, JSS College of Pharmacy, Mysore. | |
| Medicinal plants are vital sources of easily accessible remedy used in the countryside healthcare system. This study aimed to find and make record of plants that are used for medicinal therapy by three communities living in Cherangani Hills. So far no single study has documented medicinal plants as a whole in the area. Ethnobotanical data were obtained through interviewing informants using semi-structured questionnaires and extracting information from journals and books. Descriptive statistical analysis was applied to describe the data. Overall 296 plant species from 80 families and 191 genera were identified. Asteraceae family was the most dominant, representing 10.7% of the total plant species recorded. Roots (35.9%) represented the most commonly used parts of the plant. The commonly used method of preparation was decoction (54.9%). The reported diseases were classified into 14 diverse ailment groups out of the 81 health conditions on their underlying user reports. Rural communities in Cherangani Hills are rich sources of plants with medicinal properties. Therapeutic uses of the compiled plants provide basic information that can aid scientists to conduct additional research dedicated to conservation of species and pharmacological studies of species with the greatest significance. | |
| **Workshop:** Dr. Sudha Parimala | **4 HOURS** |
| Ayurvedic formulations processing (Asava, Aristha, Bhasma, Vati) | |

| **Lecture -III** | **2 HOURS** |
|---|---|
| Important Medicinal Plants mentioned in ancient texts | |

| |
|---|
| **Speaker**: Dr.Salma Khanum. HOD, Al-Ameen College of Pharmacy, Bengaluru. |
| **Workshop:** Dr. Sudha Parimala **4 HOURS** |
| Field visit to medicinal plant garden |

| **Lecture -IV** **2 HOURS** |
|---|
| **Important Aromatic Plants mentioned in ancient texts** |
| Aromatic and medicinal plants, through their secondary metabolism, provide a complex mixture of volatile molecules known as essential oils. These volatile molecules exert antibacterial activity that has been used in folk medicine for centuries. |
| **Speaker**: DR. Kotresh Kumar, Director, CIMAP Uppal, Hyderabad |
| **Workshop:** Dr. G. Kalpana **4 HOURS** |
| Field visit to Aromatic plants Garden. |

| **Lecture -V** **2 HOURS** |
|---|
| Good Cultivation and Collection Practices guidelines-WHO, NMPB-AYUSH, Voluntary Certification Scheme for Medicinal Plant Produce, Conservation of rare and endangered traditional plants |
| **Speaker**: DR. S. Shasidhara, Retd. Principal, Government College of Pharmacy, Bengaluru |
| **Workshop:** Dr. G. Kalpana **4 HOURS** |
| Standardization of few marketed herbal formulations like churna, Bhasma. |

| **Lecture -VI** **2 HOURS** |
|---|
| **Value added products** |
| AYUSH Products, food, nutraceuticals, cosmetics and agrochemicals, Entrepreneurship and start up opportunities in Plants (Licensing and manufacturing) |
| **Speaker**: DR. Gopal, Mother Theresa College, Pondicherry |
| Nutraceutical is a fledgling field emerging swiftly due to rising awareness of the potential benefits of dietary supplements used to complement drug treatment. Three-dimensional printing (3DP) is a new-fangled drug delivery system that enables the designing of complex structures according to the needs of each individual. The distinctive characteristics of 3DP are beginning to come to the fore due to advances achieved in other industries and currently riding the wave in the field of nutraceuticals. This study seeks to provide recent breakthroughs in the development of nutraceuticals using various 3D printing techniques and serves as a guide to formulators in terms of nutraceutical development scenarios to allow unabridged benefits of personalized nutrition to patients. Understanding the primary drivers of the nutraceutical market, together with a consistent and well-defined regulatory framework, will open up new avenues for 3D printed nutraceutical innovation, diversification, and segmentation. |
| **Workshop**: Dr. G. Kalpana **4 HOURS** |
| Extraction & Isolation of soluble and insoluble fibre from Carrot, ApplePomace. |

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EAMCET Code: RBVW | PGECET Code: RBVW1

Certificate course- (INDIAN TRADITIONAL MEDICINE) –2020-21

**LIST OF PARTICIPANTS**

| S.NO | NAME |
|---|---|
| 1 | S.Ashwitha |
| 2 | R. Aarthi |
| 3 | M.Aishwarya |
| 4 | V.Akansha |
| 5 | Amreen Fatima |
| 6 | **Amutul Rahman** |
| 7 | Anjali Jingid |
| 8 | M.Ankitha |
| 9 | T.Anuhya |
| 10 | M.Anusha |
| 11 | Anusree.p |
| 12 | A.Vani |
| 13 | H.Ashritha |
| 14 | M.Bhanu sri |
| 15 | J.Bhavana |
| 16 | CH.Bhavani |
| 17 | Katika blessy ruth |
| 18 | Bushra Fatima |
| 19 | J.Chandana |
| 20 | G.Chandana |
| 21 | P.Chandini |
| 22 | K.Dhana laxmi |
| 23 | Hadia Anjum |
| 24 | Hajira Yasmeen |
| 25 | S.Jayasri |
| 26 | **K.Durga** |
| 27 | Gujja.Vaishanavi |
| 28 | B.Keerthana |

| | |
|---|---|
| 29 | B Rakshitha |
| 30 | Sai Saranya |

# RBVRR WOMEN'S COLLEGE OF PHARMACY

3-4-343, Barkathpura, Hyderabad - 500027, Ph: 040-27563065

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EAMCET Code: RBVW PGECET Code: RBVW1

Date :- 3/10/20 to 10/10/20

ATTENDANCE FORM : CODE:ITMC001 (INDIAN TRADITIONAL MEDICINE) --2020-21

| S.no | NAME | COLLEGE | Day -1 | Day-2 | Day -3 | Day -4 | Day -5 | Day -6 |
|---|---|---|---|---|---|---|---|---|
| 1 | S Ashwitha | | Ashwitha | Ashwitha | Ashwitha | Ashwitha | Ashwitha | Ashwitha |
| 2 | R Aarthi | RBVRR | Aarthi | Aarthi | Aarthi | Aarthi | Aarthi | Aarthi |
| 3 | M Aishwarya | RBVRR | Aishwarya | Aishwarya | Aishwarya | Aishwarya | Aishwarya | Aishwarya |
| 4 | V Akansha | RBVRR | Akanksha | Akanksha | Akanksha | Akanksha | Akanksha | Akanksha |
| 5 | Amreen Fatima | RBVRR | Ameen | Ameen | Ameen | Ameen | Ameen | Ameen |
| 6 | Amutul Rahman | RBVRR | Amtul | Amtul | Amtul | Amtul | Amtul | Amtul |
| 7 | Anjali Jingo | RBVRR | Anj | Anj | Anj | Anj | Anj | Anj |
| 8 | M Ankitha | R.B.V.R.R | Ankitha | Ankitha | Ankitha | Ankitha | Ankitha | Ankitha |
| 9 | T Anuhya | R.B.V.R.R | Anuhya | Anuhya | Anuhya | Anuhya | Anuhya | Anuhya |
| 10 | M Anusha | R.B.V.R.R | Anusha | Anusha | Anusha | Anusha | Anusha | Anusha |
| 11 | Anusree.p | R.B.V.R.R | Anup | Anup | Anup | Anup | Anup | Anup |
| 12 | A Vani | R.B.V.R.R | Vani | Vani | Vani | Vani | Vani | Vani |
| 13 | H Ashritha | R.B.V.R.R | Ashritha | Ashritha | Ashritha | Ashritha | Ashritha | Ashritha |
| 14 | M Bhanu sri | R.B.V.R.R | Bhanusri | Bhanusri | Bhanusri | Bhanusri | Bhanusri | Bhanusri |
| 15 | J Bhavana | R.B.V.R.R | Bhavana | Bhavana | Bhavana | Bhavana | Bhavana | Bhavana |
| 16 | CH.Bhavani | | Bhavani | Bhavani | Bhavani | Bhavani | Bhavani | Bhavani |
| 17 | Ketika blessy ruth | | Blessy | Blessy | Blessy | Blessy | Blessy | Blessy |
| 18 | Bushra Fatima | | Bushra | Bushra | Bushra | Bushra | Bushra | Bushra |
| 19 | J Chandana | R.B.V.R.R | Chandana | Chandana | Chandana | Chandana | Chandana | Chandana |
| 20 | G Chandana | R.B.V.R.R | Chandana | Chandana | Chandana | Chandana | Chandana | Chandana G. |
| 21 | P Chandini | | Chandini | Chandini | Chandini | Chandini | Chandini | Chandini |
| 22 | K Dhana laxmi | | Dhana | Dhana | Dhana | Dhana | Dhana | Dhana |
| 23 | Hadia Anjum | | Hadia | Hadia | Hadia | Hadia | Hadia | Hadia |
| 24 | Hajira Yasmeen | R.B.V.R.R | Hajira | Hajira | Hajira | Hajira | Hajira | Hajira |
| 25 | S Jayasri | R.B.V.R.R | Jayasri | Jayasri | Jayasri | Jayasri | Jayasri | Jayasri |
| 26 | K.Durga | RBVRR | Durgak. | Durgak. | Durgak. | Durgak. | Durgak. | Durgak. |
| 27 | Gujja Vaishanavi | RBVRR | Vaishnu | Vaishnu | Vaishnu | Vaishnu | Vaishnu | Vaishnu |
| 28 | B Keerthana | R.B.V.R.R | Keerthana | Keerthana | Keerthana | Keerthana | Keerthana | Keerthana |
| 29 | B Rakshitha | RBVRR | Rakshitha | Rakshitha | Rakshitha | Rakshitha | Rakshitha | Rakshitha |
| 30 | Sai Saranya | RBVRR | Saranya | Saranya | Saranya | Saranya | Saranya | Saranya |

College Code: 1706

# RBVRR WOMEN'S COLLEGE OF PHARMACY

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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<br>Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy | 27thAugust 2018 & 28th August 2018 |
| 2. Raju Bhupathi Raja<br>IP Attorney, Hyderabad | 29th August 2018 & 30th August 2018 |
| 3. Dr. Priya Anish Mathews<br>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.

**List of Participants**

| S.no | Name of the participant |
|---|---|
| **1** | Ganata Nikhita |
| **2** | Asma Ul Husna |
| **3** | Gade Bhanusri |
| **4** | E veena Rani |
| **5** | Thumma Swetha Reddy |
| **6** | Nidha Begum |
| **7** | Uzma Afreen |
| **8** | B Gresshma Paul |
| **9** | Degala Vishwanayani |
| **10** | Baddam Pranaya Ragini |
| **11** | V Swetha |

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## Attendance Sheet of Certificate Course in Pharmaceutical Regulatory Affair (2018-2019)

| S.no | Name of the participant | 27/8/18 | 28/8/18 | 29/8/18 | 31/8/18 | 2/9/18 | 3/9/18 |
|---|---|---|---|---|---|---|---|
| 1 | Ganata Nikhita | Nikhita | Nikhita | Nikhita | Nikhita | Nikhita | Nikhita |
| 2 | Asma Ul Husna | Husna | Husna | Husna | Husna | Husna | Husna |
| 3 | Gade Bhanusri | Bhanusri | Bhanusri | Bhanusri | Bhanusri | Bhanusri | Bhanusri |
| 4 | E veena Rani | Veena | Veena | Veena | Veena | Veena | Veena |
| 5 | Thumma Swetha Reddy | Swetha | Swetha | Swetha | Swetha | Swetha | Swetha |
| 6 | Nidha Begum | Nidha | Nidha | Nidha | Nidha | Nidha | Nidha |
| 7 | Uzma Afreen | Afreen | Afreen | Afreen | Afreen | Afreen | Afreen |
| 8 | B Gresshma Paul | Greeshma | Greeshma | Greeshma | Greeshma | Greeshma | Greeshma |
| 9 | Degala Vishwanayani | Vishwanayani | Vishwanayani | Vishwanayani | Vishwanayani | Vishwanayani | Vishwanayani |
| 10 | Baddam Pranaya Ragini | Pragini | Pragini | Pragini | Pragini | Pragini | Pragini |
| 11 | V Swetha | Swetha | Swetha | Swetha | Swetha | Swetha | Swetha |

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

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| **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.

List of Participants

| S.no | Name of the student |
|---|---|
| 1 | Ganta nikitha |
| 2 | Asma Yl Husna |
| 3 | Gade Bhanusri |
| 4 | Thumma Swetha Reddy |
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## Attendance Sheet of Certificate Course in Design of Experiments in Pharmaceutical Development (2018-2019)

| S.no | Name of the participant | 11/6/18 | 12/6/18 | 13/6/18 | 14/6/18 | 15/6/18 |
|---|---|---|---|---|---|---|
| 1 | Ganta nikitha | Nikitha | Nikitha | Nikitha | Nikitha | Nikitha |
| 2 | Asma Yl Husna | Husna. | Husna. | Husna | Husna | Husna |
| 3 | Gade Bhanusri | Bhanusri | Bhanusri | Bhanusri | Bhanusri | Bhanusri |
| 4 | Thumma Swetha Reddy | Swetha | Swetha | Swetha | Swetha | Swetha |
| 5 | Nidha Begum | Nidha | Nidha | Nidha | Nidha | Nidha |
| 6 | Uzma Afreen | Afreen | Afreen | Afreen | Afreen | Afreen |
| 7 | B Greeshma Paul | Greeshma | Greeshma | Greeshma | Greeshma | Greeshma |
| 8 | Degala Vishwanayani | Vishwanayani | Vishwanayani | Vishwanayani | Vishwanayani | Vishwanayani |
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| 10 | V sweetha | Sweetha | Sweetha | Sweetha | Sweetha | Sweetha |