Academic Year 2024 – 2025

Class: IV-II

Program: B. Pharm

Name of the Course: **PHARMACEUTICAL REGULATORY SCIENCE**

COURSE FILE CONTENTS

Vision

To be recognized as an Institute of excellence, imparting quality pharmacy and healthcare education, producing competent professionals with research orientation and entrepreneurial attitude, capable of meeting the demands of the Industry and serving the Society.

Mission

M1: To provide a conducive environment for student centric teaching - learning process to achieve academic excellence.

M2: To foster among students the attitude of research, innovation and entrepreneurship.

M3: To establish effective Industry – Institute interaction with the Pharmaceutical and Healthcare sectors.

M4: To inculcate ethical and moral values among students to make them responsible to meet the needs of the society.

BALAJI COLLEGE OF PHARMACY, ANANTAPURAMU
(Approved by AICTE, PCI, New Delhi and affiliated to JNTUA)
Rudrampeta Bypass, Sanapa Road, Anantapuramu, Andhraprades-515002

File No.SCHE-JNTA/912/2024-JNTUA-EHE73

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

ACADEMIC CALENDAR 2024-25

B.Pharm IV Year I & II Semesters
(for 2021 admitted batch)

Description	From To	No. of weeks/days
I Semester		
Commencement of Class work	**05.08.2024**	-
Instruction Period for the Semester	05.08.2024 to 30.11.2024	(17 weeks)
Examinations:		
I Mid-term Examinations	26.09.2024 to 28.09.2024	(03 Days)
II Mid-term Examinations	28.11.2024 to 30.11.2024	(03 Days)
End laboratory Examinations:	02.12.2024 to 07.12.2024	(01 week)
End Theory Examinations:	09.12.2024 to 21.12.2024	(02 weeks)
Commencement of Class Work for IV Year B.Pharm II semester	**23.12.2024 (Monday)**	
Declaration of results for IV-I	**17.01.2025**	

II Semester		
Commencement of Class work	**23.12.2024**	-
Instruction Period for the Semester (include project work)	23.12.2024 to 19.04.2025	(17 weeks)
Examinations:		
I Mid-term Examinations	21.02.2025 to 22.02.2025	(02 Days)
II Mid-term Examinations	18.04.2025 to 19.04.2025	(02 Days)
End Theory Examinations:	21.04.2025 to 30.04.2025	(10 Days)
Project work Viva Voce Examinations:	01.05.2025 to 03.05.2025	(03 Days)
Declaration of results for IV-II	**08.05.2025**	

Note:

- The Mid-term Examinations should be conducted and completed as per the schedule given.
- For slippage of 100 instruction days in 17 weeks due to any unavoidable reasons, compensation can be made by conducting class work on second Saturdays, Sundays and other holidays, except on National Holidays and important festivals.

Digitally Signed by Eddula Keshava Reddy
Date: 27-06-2024 17:22:04
Reason: Approved

Date: 27.06.2024

DIRECTOR OF EVALUATION

PROGRAM: B Pharmacy

PROGRAMEDUCATIONALOBJECTIVES (PEO)

Fundamental Knowledge:

- To produce pharmacy graduates with strong fundamental concepts and high technical competence in pharmaceutical sciences and technology, who shall be able to use these tools in pharmaceutical industry and/or institutes where ever necessary for success.
- To provide students with a strong and well-defined concept in the various fields of pharmaceutical sciences viz., Pharmaceutics, Pharmaceutical chemistry, Pharmacology and Pharmacognosy according to the requirement of pharmaceutical industries, community and Hospital Pharmacy and also to develop a sense of teamwork and awareness amongst students towards the importance of interdisciplinary approach for developing competence in solving complex problems in the area of Pharmaceutical Sciences.

PracticeandCare:

- To promote the development of trained human resource in Pharmaceutical Sciences for dissemination of quality education with highly professional and ethical attitude, strong communication skills, effective skills to work in a team with a multidisciplinary approach.
- To generate potential knowledge pools with interpersonal and collaborative skills to identify, assess and formulate problems and execute the solution in closely related pharmaceutical industries.
- To train the students to contribute towards health care system and counseling for prophylaxis and prevention of diseases

LifelongLearningandInnovation:

- To encourage the students to participate in life-long learning process for a highly productive career and to relate the concepts of Pharmaceutical Sciences
  Towards serving the cause of the society.
- Developinginnovativeideasandapproachestoenhancequalityandovercomeprofessionalbarriers.
- Engagingincreativethinkingtoenvisionbetterwaysofachievingprofessionalgoals.

PROGRAM OUTCOMES (POs)

1. Comprehensive Pharmacy and Clinical Knowledge: Demonstrate proficiency in core knowledge and skills related to pharmaceutical, biomedical, clinical, and epidemiological sciences. This includes expertisein areas supporting quality pharmacy practice, such as pharmaceutics, medicinal chemistry, pharmacokinetics, pharmacodynamics, pharmacology, pathophysiology, Pharmacotherapeutics, and pharmaceutical care.

2. Patient-Centered Care: Provide personalized care to diverse patients, incorporating the best available evidence and considering patients' individual circumstances. Develop, modify, implement, document, and monitor pharmacotherapy care plans independently or as part of healthcare teams.

3. Problem Solving and Decision Making: Utilize observational, analytical,and critical thinking skills to identify and address pharmacotherapyproblems. Make informed decisions based on evidence-based practice.

4. Social and Cultural Awareness: Recognize the social determinants of health and respect patients' cultural, social, and religious perspectives. Promote safe and appropriate medication use within society. Demonstrate self-awareness and a commitment to lifelong learning, reflecting on personal knowledge, experiences, values, attitudes, biases, and beliefs.

5. Professionalism: Exhibit professional ethics, attitudes, and behaviors, including patient advocacy, altruism, accountability, compassion, Integrity, and respect for others. Understand, analyze, and communicate the value of professional roles in society, such as healthcare professionals, health promoters, educators, managers, employers, and employees.

7. Innovation and Entrepreneurship: Engage in innovative activities, using creative thinking to envision improved ways of achieving professional goals. Apply scientific inquiry and critical thinking in daily practice. Acquire the skills needed to start a community pharmacy or a chain of community pharmacies with patient care services.

8. Confidentiality and Professional Ethics: Practice ethically, maintainingpatient confidentiality, addressing errors in care and professional misconduct, and adhering to principles of ethical research. Apply ethical principles when making decisions and take responsibility for the outcomes associated with those decisions.

9. Interpersonal and Communication Skills: Demonstrate effective interpersonal written and verbal communication skills, adapting to socioeconomic, cultural, and situational factors. Educate families, patients, caregivers, and other healthcare professionals. Collaborate effectively within healthcare teams and provide consultation to regulatoryagencies and policy makers.

10. Clinical Pharmacist and Society: Apply contextual knowledge to assesssocietal healthcare needs and demonstrate effective planning abilities to address healthcare practice issues. Educate and raise awareness among patients regarding health aspects and disease prevention, providing cost-effective drug therapy.

11. Environment and Sustainability: Understand the impact of professional pharmacy solutions in societal and environmental contexts. Demonstrate knowledge of and advocate for sustainable development.

12. Practice-Based Learning and Improvement: Evaluate and improve patient care and pharmacy services. Demonstrate self- assessment skills and a commitment to lifelong learning for high-quality care. Locate, appraise, and integrate evidence from scientific studies to enhance the quality of care and services. Effectively utilize information, informatics, and technology to optimize learning and patient care.

FACULTY DETAILS

Name of the Faculty:	Dr K V Lalitha M.Pharm., Ph.D
Designation:	Professor
Department:	Department of Pharmaceutical Analysis
COURSE NAME:	Pharmaceutical Regulatory Science – Theory
COURSE CODE	BP804ET (ELECTIVE THEORY)
PROGRAM:	B. Pharm. (Regular/ Lateral)
SEMESTER:	Eight
Academic Year:	**2024-2025**

Scope & Objectives:

Scope:

This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, and UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives:

Upon completion of the subject student shall be able to;

1.Know about the process of drug discovery and development

2.Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

3.Know the regulatory approval process and their registration in Indian and international markets

SYLLABUS

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory) 45Hours

Course content:

Unit I 10Hours

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II 10Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III 10Hours

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV 08Hours

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safetymonitoring in clinical trials

Unit V 07Hours

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Summary:

'Pharmaceutical Regulatory Science – Theory' is a course offered in the eighth semester of B. Pharm program at Balaji college of Pharmacy, Ananthapuramu, AndhraPradesh.

References:

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, NiraliPrakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / SandyWeinberg. By John Wiley & Sons.Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng.

B. PHARM COURSE SCHEME- SEMESTER VIII

Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams Marks	Sessional Exams Duration	Total	Marks	Duration	
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardization of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812ET	Dietary Supplements and Nutraceuticals – Theory							
BP813PW	Project Work	-	-	-	-	150	4 Hrs	150
BP814MC	Essence of India Traditional Knowledge[$]	-	-	-	-	-	-	-
BP815CV	Comprehensive Viva-voce[$] - VII	-	-	-	-	-	-	-
	Total	40	60	4 Hrs	100	450	16 Hrs	550

[$] Non University Examination(NUE) and shall be graded as satisfactory (50% and above) / unsatisfactory (less than 50%)

Programme Outcomes (PO)

PO 1: Pharmacy knowledge: Apply the knowledge of basic molecular biology, drug mechanism, and science of various systems of human body, fundamental principles of analytical chemistry, preparation of different dosage forms, natural drugs and monographs of inorganic drugs in pharmacy.

PO 2: Planning abilities: Demonstrate effective planning abilities in pharmaceutical industry through resource & time management, delegation skills and organizational skills to achieve goal.

PO 3: Problem analysis: Develop ability for in-depth analytical and critical thinking in order to identify, formulate, and solve the issues related to Pharmaceutical Industry, Regulatory Agencies, Hospital and Community Pharmacy.

PO 4: Modern tool usage: Apply the foundation of pharmaceutical science in formulation technology, synthetic knowledge of modern pharmacy computing tools uses as per the requirement of pharmaceutical sectors within the constraints.

PO 5: Leadership skills: Exhibit leadership quality, team spirit with motivational capability when planning for fulfilment of professional and social responsibilities to facilitate improvement in health and wellbeing.

PO 6: Professional identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, educators, managers, employers, employees).

PO 7: Pharmaceutical ethics: Demonstrate behaviour that recognizes cultural and personal variability in values, communication and lifestyles. Honour personal values and apply ethical principles in professional and social contexts. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

PO 8: Communication: Demonstrate effective communication with the pharmacy community and with society at large such as being able to comprehend and write effective reports, make effective presentations and documentation to give and receive clear instructions.

PO 9: The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

PO 10: Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

PO 11: Entrepreneurial skill: Exhibit effective entrepreneurial skills in the field of pharmacy to analyse the market potential and grab opportunities**.**

PO 12: Lifelong learning: Develop an aptitude for lifelong learning in the broadest context of technological change. Develop the decision-making ability for selection of higher studies in pharmaceutical sciences and allied fields.

COURSE OUT COMES (CO):

B. PHARM- COURSE OUTCOMES (PCI) REGULATION: R19

CO-1:Able to understand regulatory concepts, regulatory approval process, regulatory authorities and registration of pharmaceuticals in international markets.

CO-2: Gain knowledge on steps for drug discovery, drug development, and generic drug product development.

CO-3: Able to understand regulatory approval process for new drug and generic drug and different regulators in world.

CO-4: Knowledge on procedures for registration of Indian drug products in overseas market, CTD.

CO-5: Knowledge on developing clinical trial protocols, ethics committee, monitoring clinical trials and pharmacovigilance

CO-6: Knowledge on terminology in regulatory concepts, orange book, codeof federal regulatory etc.

SPECIFIC LEARNING OUTCOMES (SLO) SEMESTER VIII (PCI)

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)		
SLO1/8	UNIT I	Gain knowledge on steps for drug discovery, drug development, and generic drug product development.
SLO2/8	UNIT II	able to understand regulatory approval process for new drug and generic drug and different regulators in world
SLO3/8	UNIT III	Knowledge on procedures for registration of Indian drug products in overseas market, CTD.
SLO4/8	UNIT IV	Knowledge on developing clinical trial protocols, ethics committee, monitoring clinical trials and pharmacovigilance
SLO5/8	UNIT V	knowledge on terminology in regulatory concepts, orange book, codeof federal regulatory etc.

COURSE PLAN

DELIVERY METHODS:
Power Point Presentation, Tutorials, Video Lectures, Design exercises, assignments, and Interactive session, viva voce.

COVERAGE:

Unit 1 by: - Power Point Presentation, Hand notes, Video Lectures, assignments.

Unit 2 by: - Power Point Presentation, Hand notes, Video Lectures, assignments, Interactive session.

Unit 3 by: - Power Point Presentation, Hand notes, Video Lectures, assignments, Design exercises, assignments.

Unit 4 by: - Power Point Presentation, Hand notes, Video Lectures, assignments, Interactive session.

Unit 5 by: -Power Point Presentation, Hand notes, Video Lectures, assignments, Interactive session

BEYOND SYLLABUS:

GPAT Exam Preparation

Group Discussion

LESSONPLAN

Academic Year: 2024–2025 Class: IV SEM: II

Program: B. Pharmacy Duration of the year: 2024 - 2025

Name of the Course: **PHARMACEUTICAL REGUATORY SCIENCE**

Prescribed Hours: **Theory:** 3hrs /Week.

Scheduled Date: 23/12/2024 to 30/04/2025

S.No	Chapter name	Topic	No. of hours	Name of the faculty
1	UNIT 1	**New Drug Discovery and development** Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug Product development.	10	Dr. K V Lalitha Professor
2.	UNIT 2	**Regulatory Approval Process** Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an Approved NDA / ANDA. **Regulatory authorities and agencies** Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)	10	Dr. K V Lalitha Professor
3.	UNIT 3	**Registration of Indian drug product in overseas market** Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN	10	Dr. K V Lalitha Professor

		Common Technical Document (ACTD) research.		
4.	**UNIT 4**	**Clinical trials** Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safetymonitoring in clinical trials	**8**	**Dr. K V Lalitha Professor**
5.	**UNIT 5**	**Regulatory Concepts** Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	**7**	**Dr. K V Lalitha Professor**

Program: B. Pharmacy Duration of the year: 2024 - 2025

Name of the Course: **PHARMACEUTICAL REGUATORY SCIENCE**

Prescribed Hours: **Theory:** 3 /Week

Scheduled Date: 23/12/2024 to 09/05/2025

ASSIGNMENTS

ASSIGNMENTTOPIC	Course Outcome	BTL
Assignment1		
Stages of drug discovery	**C 804ET.1**	Remembering
Approval processes and timelines involved in Investigational New Drug (IND)	**C 804ET.2**	Applying
Assignment2		
Common Technical Document (CTD)	**C 804ET.3**	Analyzing
Institutional Review Board	**C 804ET.4**	Understanding
Assignment3		
Orange book	**C 804ET.5**	Understanding

Format of the assignment:

1. Minimum& Maximum number of pages.
2. It shall be written draft copy.
3. Name and signature of the student.
4. Assignment can be combined seminar presentation at the end of the semester.
5. Time allocatedforseminarmaybe8+2Min.

CodeNo: **BP804ET** Roll.No:

Balaji College of Pharmacy, Ananthapuramu.

IV-Year II-sem B.Pharmacy

I-Mid Examinations, FEB–2025

SUB: BP804ET.PHARMACEUTICAL REGULATORY SCIENCE

Time: 01:30Hrs **Max.Marks: 30**

I. ANSWER ALL THE QUESTION **2x5=10 MARKS**

S.No	Question	Marks	Course Outcome	BTL
1.	Define Innovator Drug Product?	2M	CB804.1	Remembering
2.	Write about Timeline and types of IND?	2M	CB804.2	Analyzing
3.	What are various Regulatory Authorities in drug discovery?	2M	CB804.2	Remembering
4.	Define DMF?	2M	CB804.3	Remembering
5.	What do you mean by eCTD?	2M	CB804.3	Remembering

II. Answer any one of the following questions **1x 10=10 MARKS**

S.No	Question	Marks	Course Outcome	BTL
6.	Define the concept of Generics and explain the protocols involved in generic product development?	10M	CB804.2	Analyzing & Remembering
7.	Discuss the various modules and requirements of electronic common technical document (e CTD)	10M	CB804.3	Remembering & Evaluating

III. Answer any two of the following questions **2x 5=10MARKS**

S.No	Question	Marks	Course Outcome	BTL
8.	Write a short note on regulatory Authorities worked in Australia and Japan	5M	CB804.2	Remembering
9.	What are Various Steps involved in Preclinical Studies	5M	CB804.1	Understanding & Evaluating

10.	Write a note on Drug development Process	**5M**	**CB802.1**	Remembering & Understanding

Course Outcome analysis:

CO	Total CO Marks	%CO
CB804.1	12M	27%
CB804.2	19M	42%
CB804.3	14M	31%
CB804.4	0M	0%
CB804.5	0M	0%
TOTAL	45M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	Taxonomy Marks	%Taxonomy
Remember	25M	56%
Understand	6M	13%
Apply	0M	0%
Analyze	7M	16%
Evaluate	03M	6%
Create	0M	0%
TOTAL	45M	100%

CodeNo: **BP804ET** Roll.No:

Balaji College of Pharmacy, Ananthapuramu.

IV-Year II-Sem B.Pharmacy

II-Mid Examinations, APRIL–2025

SUB: BP804ET.PHARMACEUTICAL REGULATORY SCIENCE

Time: 01:30Hrs **Max.Marks: 30**

I. ANSWER ALL THE QUESTION **2x5=10 MARKS**

S.No	Question	Marks	Course Outcome	BTL
1.	Define Pharmacovigilance?	2M	CB804.5	Remembering
2.	Write the role of Purple book?	2M	CB804.5	Analyzing
3.	What is the importance informed consent form?	2M	CB804.4	Remembering
4.	Define Clinical trial and note on Phase II?	2M	CB804.4	Remembering
5.	What are the various terms used in Regulatory Affairs?	2M	CB804.5	Remembering

II. Answer any one of the following questions **1x 10=10 MARKS**

S.No	Question	Marks	Course Outcome	BTL
6.	(a)Define Federal Register, briefly write about the functions of the register? (b)Define Orange book and Explain the role of this book.	10M	CB804.5	Analyzing & Remembering
7.	What do you mean by Clinical Trail Protocol? Explain the Various steps involved in clinical Trial protocols development.	10M	CB804.4	Remembering & Evaluating

III. Answer any two of the following questions **2x 5=10MARKS**

S.No	Question	Marks	Course Outcome	BTL
8.	Write a short note on GCP Obligations and explain with suitable example	5M	CB804.4	Remembering

9.	What are Various Laws and acts involved in Drug Regulatory Affairs? Explain.	**5M**	**CB804.5**	Understanding & Evaluating
10.	Write a note on Roles and Responsibilities of IRB / IEC	**5M**	**CB804.4**	Remembering & Understanding

Course Outcome analysis:

CO	Total CO Marks	%CO
CB804.1	0M	0%
CB804.2	0M	0%
CB804.3	0M	0%
CB804.4	24M	53%
CB804.5	21M	47%
TOTAL	45M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	Taxonomy Marks	%Taxonomy
Remember	26M	58%
Understand	5M	11%
Apply	0M	0%
Analyze	07M	16%
Evaluate	07M	16%
Create	0M	0%
TOTAL	45M	100%

BALAJI COLLEGE OF PHARMACY :: ANANTAPUR

B.PHARMACY – IV-YEAR-II-SEM -2024-2025 (R19)

MID I EXAMINATIONS AVERAGE MARKS AWARD LIST

Name of the Sub: **Sub. Code:** **(Theory)**

Sl No.	H.T.No	Name Of The Student	MID-I		MID-II		Avg	Continuous Mode	Total (25M)
			30M	15 M	30 M	15M			
1	21T11R0001	Ajay Kumar Madiga	26	13	28	14	14	8	22
2	21T11R0002	Ajaykumar Sanipiralla	22	11	26	13	13	9	22
3	21T11R0003	Akhila Sejala	27	13.5	27	13.5	14	10	24
4	21T11R0004	Akhila Uppara	28	14	28	14	14	10	24
5	21T11R0005	Anusha Chennavaram	29	14.5	28	14	14	9	23
6	21T11R0006	Arju Chalam	26.5	13.5	28	14	14	9	23
7	21T11R0007	Arshiya Dafedar	27	13.5	28	14	14	9	23
8	21T11R0008	Bharath Rao Sindhe	25	12.5	28	14	13	10	23
9	21T11R0009	Bhargav Dandina	26	13	25	13	13	6	19
10	21T11R0010	Bhargavi Gorakappa Gari	25	12.5	28	14	13	9	22
11	21T11R0011	Bhavana Malarapu	26	13	26	13	13	10	23
12	21T11R0012	Bhavana Vuruvakili	25	12.5	27	13.5	13	10	23
13	21T11R0013	Bhavani Derangi	28.5	14.5	28	14	14	10	24
14	21T11R0014	Bhumika Yerikala	26	13	29	14.5	14	10	24
15	21T11R0015	Chaithra K	24.5	12.5	28	14	14	9	23
16	21T11R0016	Chintu Naik R	18.5	10	24	12	11	6	17
17	21T11R0017	Deepika Rani Siraalla	27	14	26	13	13	10	23
18	21T11R0018	Deekshitha N	26.5	13.5	27	13.5	14	9	23
19	21T11R0019	Deepthi G K							
20	21T11R0020	Divya Mala Basam	26.5	13.5	26	13	13	10	23
21	21T11R0021	Divyasree Bachu	27	13.5	27	13.5	14	10	24
22	21T11R0022	Fouziya Kattubadi	26.5	13.5	27	13.5	14	10	24
23	21T11R0023	Gagana S J	26	13	27	13.5	14	10	24
24	21T11R0024	Ganesh Boya	25	12.5	27	13.5	13	7	20
25	21T11R0025	Geethika Karnam							
26	21T11R0026	Gousia Shaik	27	13.5	27	13.5	14	10	24

27	21T11R0027	Gousiya Banu Benki	28	14	28	14	14	10	24
28	21T11R0028	Gowthami K S							
29	21T11R0029	Hafijabee Syed							
30	21T11R0030	Hajira Khanam N	26	13	28	14	14	9	23
31	21T11R0031	Harika Bachu	27	13.5	27	13.5	14	10	24
32	21T11R0032	Harshini Islapuram	26.5	13.5	28	14	14	10	24
33	21T11R0033	Hijiya Bee Gagguturu	26.5	13.5	26	13	13	10	23
34	21T11R0034	Indira Racherla	26.5	13.5	26	13	13	10	23
35	21T11R0035	Indu Pommala	26	13	25.5	13	13	10	23
36	21T11R0036	Jaithrasai Gaddam	20	10	23.5	12	11	8	19
37	21T11R0037	Jayasree Palem	26	13	27	13.5	13	9	22
38	21T11R0038	Jeevan Reddy Kona	27	13.5	27	13.5	14	8	23
39	21T11R0039	Jnana Sai P	24	12	26	13	13	8	21
40	21T11R0040	Kamalnath Reddy Gundra	24	12	24	12	12	6	18
41	21T11R0041	Kavya Sri Janagana	26	13	26	13	13	10	23
42	21T11R0042	Keerthana Bokki	28	14	27	13.5	14	9	23
43	21T11R0043	Keerthi Godditi	26	13	26	13	13	9	22
44	21T11R0044	Keerthi Jinkala	27	13.5	25.5	13	13	9	22
45	21T11R0045	Kishore Babu C	25.5	13	26	13	13	10	23
46	21T11R0046	Kushiya Dudekula	25	13	26	13	13	10	23
47	21T11R0047	Lakshmi Kammara	27	13.5	28	14	14	10	24
48	21T11R0048	Lakshmilatha K A	28	14	28	14	14	10	24
49	21T11R0049	Leelavathi Chinthakayala	26	13	27	13.5	14	10	24
50	21T11R0050	Mahalakshmi Urapasula	27	13.5	28	14	14	10	24
51	21T11R0051	Mahammad Thosif Mitaigari	22.5	11.5	26	13	13	8	21
52	21T11R0052	Manjulatha Boppi	25.5	13	28	14	14	9	23
53	21T11R0053	Meghana Ganta	25	12.5	27.5	13.5	13	10	23
54	21T11R0054	Md. Masood Shaik Bashas	25	12.5	25	12.5	13	6	19
55	21T11R0055	Mohammed Akram Shaik							
56	21T11R0056	Mohammed Sami Bar Shaik	25	12.5	26.5	13.5	13	9	22
57	21T11R0057	Mubeen Taj Achukatla	25	12.5	26	13	13	10	23
58	21T11R0058	Muzammil Khan Patan	21	10.5	24.5	12.5	12	7	19
59	21T11R0059	Naga Sai Sahithi Kaipa	22	11	14.5	7	9	6	15
60	21T11R0060	Nagarjuna Jetti	23.5	11.5	24	12	12	8	20
61	21T11R0061	Naqeeba Banu Syeda	27	13.5	26	13	13	10	23

62	21T11R0062	Narendra Golla	24	12	24	12	12	7	19
63	21T11R0063	Naveen Kumar Mangala	27	13.5	27.5	14	14	10	24
64	21T11R0064	Navya K	26.5	13.5	26	13	13	10	23
65	21T11R0065	Neeha Duvvur	26	13	27.5	14	14	10	24
66	21T11R0066	Neha Parvez Shaik	25	12.5	26	13	13	10	23
67	21T11R0067	Nikhil Avinash Gurugundla							
68	21T11R0068	Noorjahan Khaji	26	13	26	13	13	9	22
69	21T11R0069	Pallavi Thippanna Gari	26	13	26	13	13	10	23
70	21T11R0070	Pavan Kumar Sake							
71	21T11R0071	Pavithra Mallireddy	26	13	26	13	13	8	21
72	21T11R0072	Pedda Ezra Pradeep Dudekula	24.5	12.5	25	12.5	13	7	20
73	21T11R0073	Pranitha Gunivantla	26	13	26	13	13	9	22
74	21T11R0074	Pujitha Mallepogula	26.5	13.5	27.5	14	14	9	23
75	21T11R0075	Raju Naik Vadithya	19.5	10	26	13	12	7	19
76	21T11R0076	Rakhiya Mehanoor Pathan	26.5	13.5	27	13.5	14	9	23
77	21T11R0077	Ramya Sree G	26	13	26	13	13	9	22
78	21T11R0078	Ramya Sree Ramavath							
79	21T11R0079	Ranjitha Bai Vadithya	24	12	25	12.5	12	9	21
80	21T11R0080	Sadiq Hussain Sayed	23	12.5	26.5	13.5	13	6	19
81	21T11R0081	Sai Charan B N							
82	21T11R0082	Sai Charan V N	25.5	12.5	25.5	13	13	8	21
83	21T11R0083	Sai Nived Talari	26	13	26	13	13	8	21
84	21T11R0084	Sai Vedamsh B R	26	13	24.5	12.5	13	8	21
85	21T11R0085	Sailaja Kayapati	26.5	13.5	27.5	13.5	14	9	23
86	21T11R0086	Sakheeb Shaik	25	12.5	26	13	13	8	21
87	21T11R0087	Sameera Firdous Kolimi	25.5	13	27	13.5	13	9	22
88	21T11R0088	Sandeep Bhushan Parsham							
89	21T11R0089	Sandhya Vanganooru	25.5	13	27.5	13.5	13	10	23
90	21T11R0090	Sangeetha R	26	13	26	13	13	10	23
91	21T11R0091	Sanjay Kumar Pappu	25	12.5	26	13	13	7	20
92	21T11R0092	Santhosh Vaddi							
93	21T11R0093	Sathish Kumar D	26.5	13.5	26	13	13	7	20
94	21T11R0094	Sharanya Sai Amberker	26	13	26	13	13	9	22
95	21T11R0095	Shiva Guvvala							
96	21T11R0096	Siddaraju T	18.5	9.5	25.5	13	11	7	18
97	21T11R0097	Sree lalitha N V	26	13	26.5	13	13	10	23

98	21T11R0098	Sreeja R	26	13	26.5	13	13	10	23
99	21T11R0099	Sunitha Bhavani Jalavadi	26	13	26.5	13	13	10	23
100	21T11R00A0	Teerthini Kuruba	26.5	13.5	26.5	13.5	13	9	22
101	21T11R00A1	Teja Kummari	26	13	27	13.5	13	9	22
102	21T11R00A2	Trivikram Narepalli	26	13	25.5	13	13	7	20
103	21T11R00A3	Vaishnavi Kodipalli	27	13.5	26.5	13.5	14	9	23
104	21T11R00A4	Varsha B	27	13.5	26.5	13.5	14	8	22
105	21T11R00A5	Vasantha Golla	26.5	13.5	26.5	13.5	13	9	23
106	21T11R00A6	Vasanthi Kamatham	25	12.5	26	13	13	10	23
107	21T11R00A7	Vijay Singepalli	26.5	13.5	27	13.5	14	10	24
108	21T11R00A8	Vinila Karnatakam	26.5	13.5	27.5	14	14	10	24
109	21T11R00A9	Yamini Guduru	25	12.5	26.5	13.5	13	8	21
110	21T11R00B0	Aruna Vetti							
111	21Z71R0006	T. Bala krishna	23	12.5	25	12.5	13	7	20
112	22T15R0001	A. Mehataz	26	13	26.5	13.5	13	10	23
113	20GT1R0045	K.Tejaswini	26	13	26	13	13	10	23

QUESTION BANK

UNIT-1

Topics: Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

1. Stages of Drug Discovery:

a. What are the key steps involved in the drug discovery process?

b. How is a drug target identified during the drug discovery stage?

c. What is the significance of lead compound optimization in drug discovery?

2. Drug Development Process:

a. What are the main stages involved in the drug development process?

b. How are drug candidates selected for advancement into clinical studies?

c. What are the regulatory requirements that need to be met during drug development?

3. Pre-clinical Studies:

a. What is the purpose of pre-clinical studies in drug development?

b. What types of tests and experiments are conducted during pre-clinical studies?

c. How do pre-clinical studies contribute to the safety and efficacy assessment of a drug candidate?

4. Non-clinical Activities:

a. What are non-clinical activities in the context of drug development?

b. What is the role of non-clinical studies in determining the dosing and toxicity of a drug candidate?

c. How do non-clinical activities support the submission of an Investigational New Drug (IND) application?

5. Clinical Studies:

a. What are the different phases of clinical studies in drug development?

b. How are patients recruited and enrolled in clinical trials?

c. What are the objectives of clinical studies and what data is collected during these trials?

6. Innovator and Generics:

a. What is an innovator drug, and how does it differ from a generic drug?

b. What are the main characteristics of innovator drugs?

c. How are generic drugs approved and regulated?

7. Concept of Generics:

a. What is the concept of generics in the pharmaceutical industry?

b. How do generic drugs compare to innovator drugs in terms of safety and efficacy?

c. What are the advantages and challenges of using generic drugs in healthcare?

8. Generic Drug Product Development:

a. What is involved in the development of a generic drug product?

b. How does a generic drug developer demonstrate bioequivalence to the innovator drug?

c. What are the regulatory considerations for the approval of generic drug products?

Unit II

Topics: Regulatory Approval Process Approval processes and timelines involved in Investigational New Drug(IND),New Drug Application(NDA),Abbreviated New Drug Application(ANDA).Changes to an approved NDA /ANDA.

Regulatory authorities and agencies Overview of regulatory authorities of India, United States, Europe and Union, Australia, Japan, Canada (Organization structure and types of applications)

1. What is the regulatory approval process for an Investigational New Drug (IND)? Could you outline the key steps and timelines involved?

2.What are the requirements for submitting a New Drug Application (NDA)? How does the approval process for an NDA differ from that of an IND?

3.Can you explain the timeline for the review and approval of a New Drug Application (NDA)? What factors can impact the duration of the review process?

4.What is an Abbreviated New Drug Application (ANDA), and how does it differ from an NDA? Could you provide an overview of the approval process and associated timelines for an ANDA?

5.What are the key considerations and requirements for making changes to an approved NDA? How does the regulatory authority evaluate and approve these changes?

6.Can you describe the regulatory process for making changes to an approved ANDA? What are the timelines involved in obtaining approval for these changes?

7.Are there specific types of changes to an approved NDA or ANDA that require additional regulatory approval? If so, what are they, and how are they assessed?

8.What are the potential consequences if changes are made to an approved NDA or ANDA without obtaining proper regulatory approval?

9.Are there any recent updates or changes in the regulatory approval processes for IND, NDA, and ANDA that companies should be aware of? How have these updates affected timelines or requirements?

10.Can you provide examples of post-approval changes to NDAs or ANDAs that have had significant impacts on the pharmaceutical industry? How were these changes handled from a regulatory standpoint?

11.Can you provide an overview of the regulatory authorities in India and their organization structure?

12.What are the major regulatory authorities in the United States, and what types of applications do they oversee?

13.How does the regulatory authority structure in Europe and the European Union function? Which agencies are responsible for different types of applications?

14.Can you explain the regulatory authorities in Australia and their organizational structure? What types of applications do they regulate?

15.What are the key regulatory authorities in Japan, and how are they organized? What types of applications fall under their purview?

16.In Canada, what are the main regulatory agencies and how are they structured? Which types of applications do they handle?

17.Can you provide an overview of the different types of applications and products regulated by the regulatory authorities in India?

18.What types of applications and products are regulated by the regulatory authorities in the United States?

19.What are the different types of applications and products that come under the purview of regulatory authorities in Europe and the European Union?

20.Can you explain the types of applications and products regulated by the regulatory authorities in Australia?

21.What are the different types of applications and products that fall under the regulatory authorities in Japan?

22.In Canada, which types of applications and products are regulated by the main regulatory agencies?

23.How do the regulatory authorities in India, the United States, Europe, Australia, Japan, and Canada ensure compliance with regulations for the applications and products they oversee?

24.Can you explain the approval process for applications regulated by the regulatory authorities in India?

25.What is the general process for obtaining approval for applications overseen by the regulatory authorities in the United States?

26.How does the approval process work for applications regulated by the European regulatory authorities and agencies?

27.Can you describe the process of obtaining approval for applications regulated by the regulatory authorities in Australia?

28.What is the typical approval process for applications regulated by the regulatory authorities in Japan?

29.How does the approval process for applications regulated by the regulatory authorities in Canada usually unfold?

30.Are there any notable differences in the organization structure or approval processes of these regulatory authorities across the mentioned countries?

Unit III

Topics: Registration of Indian drug product in overseas market Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files(DMF), Common Technical Document (CTD),electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

1. What is the procedure for registering an Indian drug product in overseas markets?
2. What are the key steps involved in exporting pharmaceutical products from India?
3. Could you explain the technical documentation requirements for registering drug products in international markets?
4. What is a Drug Master File (DMF) and how does it facilitate the registration of pharmaceutical products in overseas markets?
5. What is the Common Technical Document (CTD) and why is it important in the registration process for drug products?
6. Can you provide an overview of the electronic Common Technical Document (eCTD) and its role in the export of pharmaceutical products?
7. What is the ASEAN Common Technical Document (ACTD) and how does it impact the registration of Indian drug products in ASEAN countries?
8. How can companies conduct research to gather information on the registration requirements and procedures for exporting pharmaceutical products to specific overseas markets?
9. Are there any specific regulatory authorities or bodies responsible for overseeing the registration of Indian drug products in overseas markets?
10. What are some common challenges or considerations that companies need to address when preparing for the registration and export of pharmaceutical products to international markets?

Unit IV

Topics: Clinical trials Developing clinical trial protocols, Institutional Review Board/Independent Ethics committee-formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors &Monitors, Managing and Monitoring clinical trials, Pharmacovigilance- safety monitoring in clinical trials.

1. What are the key steps involved in developing clinical trial protocols?
2. How are Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs) formed, and what are their roles in the clinical trial process?
3. What are the standard working procedures for an Institutional Review Board or Independent Ethics Committee?
4. Can you explain the informed consent process in clinical trials and its significance?
5. What are the essential components of an informed consent form in a clinical trial?
6. What are the Good Clinical Practice (GCP) obligations of investigators in a clinical trial?
7. What are the GCP obligations of sponsors in a clinical trial?
8. What are the GCP obligations of monitors in a clinical trial?
9. How are clinical trials managed and monitored throughout their duration?
10. What are the key responsibilities of a clinical trial monitor?
11. How is pharmacovigilance carried out in the context of clinical trials?
12. What are the safety monitoring procedures in place to ensure patient safety in clinical trials?
13. Can you explain the process of adverse event reporting in clinical trials?
14. How are serious adverse events handled in clinical trials?
15. What measures are taken to ensure the quality and integrity of data collected during clinical trials?

Unit V

Topics: Regulatory Concepts Basic terminology, guidance, guidelines, regulations ,Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.

1. What are regulatory concepts and why are they important in various industries?
2. Can you explain the basic terminology used in regulatory frameworks?
3. What is the difference between guidance, guidelines, regulations, laws, and acts in the context of regulatory frameworks?
4. How does the Orange Book relate to regulatory concepts and pharmaceutical industry regulation?
5. What is the Federal Register and what role does it play in the regulatory process?
6. Could you provide an overview of the Code of Federal Regulations and its significance?
7. How does the Purple Book relate to regulatory concepts and the regulation of biological products?
8. What are some key examples of laws and acts that are relevant to regulatory frameworks in specific industries?
9. How do regulatory agencies use guidance documents to enforce regulations?
10. Can you explain the process of how regulations are created and implemented?
11. What is the purpose of public comment periods in the regulatory process?
12. How do regulatory bodies ensure compliance with regulations and address non-compliance?
13. What are some common challenges faced by industries in adhering to regulatory requirements?
14. How do regulatory frameworks differ between countries or regions?

15. What are some current trends or developments in regulatory concepts that are shaping industries today?

END THEORY EXAM QUESTION PAPER (JNTUA)

25/04/2025

ode: BP804ET

R19

B.Pharm IV Year II Semester (R19) Regular & Supplementary Examinations April 2025

PHARMACEUTICAL REGULATORY SCIENCE

(B.Pharmacy)

Time: 3 hours

Max. Marks: 75

PART – A

(Compulsory Question)

*****

Answer the following: (10 X 02 = 20 Marks)

(a) What is phase II in clinical trials? 2M
(b) What are non-clinical trials? 2M
(c) Name the regulatory authorities in United states and Australia. 2M
(d) What is an investigational new drug (IND) application? 2M
(e) What are electronic common technical documents? 2M
What is Technical documentation in export of pharmaceutical products? 2M
What is informed consent process? 2M
(h) What is clinical trial protocol? 2M
What is purple book? 2M
What is federal register? 2M

PART – B

(Answer any two questions: 02 X 10 = 20 Marks)

Write the role and responsibilities of institutional review committee/ Independent ethics committees. 10M

Discuss the Approval processes and timelines involved in Investigational New Drug (IND). 10M

Explain the various drug development processes. 10M

PART – C

(Answer any seven questions: 07 X 05 = 35 Marks)

Explain the various steps involved in generic procedure development. 5M

Write the non – clinical studies in the process of New Drug Application. 5M

Write about the Overview of-regulatory authorities of Japan. 5M

Write short notes on Changes to an approved NDA / ANDA. 5M

Write a note on module and benefits of electronic common technical document. 5M

Write a note on organization of ASEAN CTD format. 5M

Write about managing and monitoring clinical trials. 5M