



BALAJI COLLEGE OF PHARMACY

Approved by A.I.C.T.E. PCI New Delhi and Affiliated to J.N.T.U.A., Ananthapuram

Sanapa Road, Alamuru (P), Rudrampeta, Ananthapuramu – 515002. (A.P.)



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0 Academic Year 2023 – 2024

Class: IV-I

Program: B. Pharm

Name of the Course: **INDUSTRIAL PHARMACY II**

COURSE FILE CONTENTS

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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.



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File No.SCHE-JNTA/1035/2023-JNTUA-EHE73

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

ACADEMIC CALENDAR 2023-24

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

Description	From To	No. of weeks/days
I Semester		
Commencement of Class work	03.10.2023	-
Instruction Period for the Semester	03.10.2023 to 27.01.2024	(17 weeks)
Examinations:		
I Mid-term Examinations	25.11.2023 to 27.11.2023	(03 Days)
II Mid-term Examinations	24.01.2024 to 27.01.2024	(03 Days)
End laboratory Examinations:	29.01.2024 to 03.02.2024	(01 week)
End Theory Examinations:	05.02.2024 to 17.02.2024	(02 weeks)
Commencement of Class Work for III Year B.Pharm II semester	19.02.2024 (Monday)	
Declaration of results for III-I	11.03.2024	

II Semester		
Commencement of Class work	19.02.2024	-
Instruction Period for the Semester	19.02.2024 to 15.06.2024	(17 weeks)
Examinations:		
I Mid-term Examinations	15.04.2024 to 17.04.2024	(03 Days)
II Mid-term Examinations	13.06.2024 to 15.06.2024	(03 Days)
End laboratory Examinations:	17.06.2024 to 22.06.2024	(01 week)
End Theory Examinations:	24.06.2024 to 06.07.2024	(02 weeks)
Commencement of Class Work for IV Year B.Pharm I semester	08.07.2024 (Monday)	
Declaration of results for III-II	27.07.2024	

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.

Date: 27-07-2023

DIRECTOR OF EVALUATION

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PROGRAM: B.Pharmacy

PROGRAM EDUCATIONAL OBJECTIVES (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.

Practice and Care:

- 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



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Lifelong Learning and Innovation:

- 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.
- Developing innovative ideas and approaches to enhance quality and overcome professional barriers.
- Engaging in creative thinking to envision better ways of achieving professional goals.



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PROGRAM: B.Pharmacy

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 expertise in 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 pharmacotherapy problems. 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, maintaining patient 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 regulatory agencies and policy makers.
- 10. Clinical Pharmacist and Society:** Apply contextual knowledge to assess societal healthcare needs and demonstrate effective planning abilities to address healthcare practice issues. Educate and raise awareness



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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.



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Course objectives

- This course will enable the student to know the process of pilot plant and scale up of pharmaceutical products.
- Upon completion of the course, the students will also get knowledge with respect to the technology transfer from lab scale to commercial batch.
- This course gives complete package of different laws and acts that regulate the operations in pharmaceutical industries.
- This course also gives an idea to the students about the regulatory requirements for new drug approval process and day-to-day operations in the pharmaceutical industries and provides the confidence to the students to take up jobs in industries.

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
C70 2.1	Summarize the scale up process in pharmaceutical Industry.	L1: Remember L2: Understand L3: Apply
C70 2.2	Review the technology transfer.	L3: Apply L4: Analyse L5: Evaluate
C70 2.3	Explain about various laws and acts that regulate Pharmaceutical industry.	L3: Apply L4: Analyse L5: Evaluate
C70 2.4	Implement the regulatory environment by Upholding good regulatory practices.	L3: Apply L4: Analyse L5: Evaluate
C70 2.5	Describe the regulations and approval process in Pharmaceutical industry.	L3: Apply L4: Analyse L5: Evaluate

BLOOMS Taxonomy- L1: Remember, L2: Understand, L3: Apply, L4: Analyse, L5: Evaluate, L6: Create



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How program outcomes are assessed:

Program Outcome		Level	Proficiency assessed by
PO1:	Pharmacy Knowledge	3	Assignments/ Internals/Viva
PO2:	Planning Abilities	2	Assignments/ Internals
PO3:	Conduct Investigations of Complex Problems	2	Assignments/ Internals/ Practicals
PO4:	Problem Analysis	3	Assignments/ Internals
PO5:	Modern Tool Usage	2	Seminars/academic activities
PO6:	Leadership Skills	3	Group discussion / Role play
PO7:	Professional Identity	3	Group discussion
PO8:	Pharmaceutical Ethics	3	Personality development seminars
PO9:	Communication	3	Students' seminars/ student -teacher interaction
PO10: :	The Pharmacist and Society	3	Group discussion / Role play
PO11: :	Environment And Sustainability	3	Students' seminars
PO12	Life-Long Learning	3	Assignments/ Internals

LEVEL: 1- Slight (Low), 2- Moderate(Medium), 3- Substantial(High)



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LESSONPLAN

Academic Year: 2023–2024

Class: IV

SEM: I

Program: B. Pharmacy

Duration of the year: 2023 - 2024

Name of the Course: **PHARMACEUTICAL MICROBIOLOGY**

Prescribed Hours: **Theory:** 3 + 1 Hrs. /Week

Scheduled Date: 01/08/2023 to 15/12/2024

S.No	Chapter name	Topic	No. of hours	Name of the faculty
1	UNIT 1	Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology	10	Mr. Venkatesh Naik V Assistant Professor
2	UNIT 2	Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation -confidentiality agreement, licensing, MoUs, legal issues	10	Mr. Venkatesh Naik V Assistant Professor
3	UNIT 3	Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs	10	Mr. Venkatesh Naik V



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		department, Responsibility of Regulatory Affairs Professionals Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.		Assistant Professor
4	UNIT 4	Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	8	Mr. Venkatesh Naik V Assistant Professor
5	UNIT 5	Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.	7	Mr. Venkatesh Naik V Assistant Professor



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BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I 10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II 10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation -confidentiality agreement, licensing, MoUs, legal issues

UNIT-III 10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.



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UNIT-IV08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V 07 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.



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Program: B. Pharmacy

Duration of the year: 2023 - 2024

Name of the Course: **INDUSTRIAL PHARMACY II**

Prescribed Hours: **Theory:** 3 + 1 Hrs./Week

Scheduled Date: 01/08/2023 to 15/12/2024

ASSIGNMENTS

ASSIGNMENT TOPIC	Course Outcome	BTL
Assignment 1		
Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation.	C 405.1	Remembering
SUPAC guidelines	C 405.2	Applying
Assignment 2		
	C 405.3	
General considerations of Investigational New Drug (IND) Application	C 405.4	Analyzing
Investigator's Brochure (IB) and New Drug Application (NDA).	C 405.5	Understanding
Assignment 3		
	C 405.1	
Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	C 405.2	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.



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4. Assignment can be combined seminar presentation at the end of the semester.
5. Time allocated for seminar may be 8+2 Min.

Balaji College of Pharmacy, Ananthapuramu.

IV Year I sem B.Pharm I Mid Examinations, **Spet-2023**

INDUSTRIAL PHARMACY II

Time: 01:30Hrs

Max. Marks: 30

S.NO	ANSWER ALL QUESTIONS	MARKS	COURSE OUTCOME	BLOOMS LEVEL
1	Differentiate between acid fast and nonacid fast bacteria	02	C 405.1	Remembering
2	Differentiate between log phase and decline phase?	02	C 405 .1	Remembering
3	What is basal media? Give example	02	C 405.2	Remembering
4	Mention the demerits of ethylene oxide sterilization?	02	C 405.2	Remembering
5	Define sterilization?	02	C 405.3	Remembering
	ANSWER ANY ONE QUESTION			
6	Explain the principle, procedure, applications and demerits of sterilization using autoclave?	10	C 405.1	Understanding
7	Draw an ultra-structure of typical bacteria. Write composition and functions of its organelles?	10	C 405.2	Creating
	ANSWER ANY TWO QUESTIONS			
8	Differentiate between gram positive and Gram negative cell wall?	05	C 405.1	Understanding



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9	Give the principle and main characteristic of phase contrast microscopy?	05	C 405.2	Understanding
10	Describe any two methods of total counting?	05	C 405.3	Evaluating

Course Outcome analysis:

CO	Total CO Marks	%CO
C 405.1	19M	42.22%
C 405.2	19M	42.22%
C 405.3	07M	15.56%
C 405.4	0M	0%
C 405.5	0M	0%
TOTAL	45M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	Taxonomy Marks	%Taxonomy
Remember	10M	22.22%
Understand	20M	44.45%
Apply	0M	0%
Analyze	0M	0%
Evaluate	05M	0%
Create	10M	11.11%



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TOTAL	45M	100%
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IV Year I sem B.Pharm II Mid Examinations, **Nov-2023**

INDUSTRIAL PHARMACY-II

Time: 01:30Hrs

Max. Marks: 30

S.NO	ANSWER ALL QUESTIONS	MARKS	COURSE OUTCOME	BLOOMS LEVEL
1	Name the technology transfer agencies in India?	02	C 405.4	Remembering
2	Mention Two functions of Port Offices of CDSCO?	02	C 405.4	Understanding
3	What are the elements of QbD?	02	C 405 .5	Analyzing
4	Define TQM? What are the key elements of TQM?	02	C 405.5	Understanding
5	Salient features of ISO 9000?	02	C 405.4	Understanding
	ANSWER ANY ONE QUESTION			
6	Explain the concepts of Total Quality Management and Quality by Design (QbD)?	05	C 405.4	Remembering
		05	C 405.4	Remembering
7	What is technology transfer? Discuss the TT protocol, process, packaging and cleaning?	05	C 405.5	Understanding
		05	C 405.5	Understanding
	ANSWER ANY TWO QUESTIONS			
8	Describe the Organization of CDSCO with f diagram?	05	C 405.4	Remembering
9	Explain six sigma concepts for Quality Improvement?	05	C 405.5	Understanding
10	Write a note on Drug Technical Advisory Board (DTAB) and its functions?	05	C 405.3	Evaluating



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Course Outcome analysis:

CO	Total CO Marks	%CO
C 405.1	0M	0%
C 405.2	0M	0%
C 405.3	05M	11.11%
C 405.4	21M	46.66%
C 405.5	19M	42.22%
TOTAL	45M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	Taxonomy Marks	%Taxonomy
Remember	17M	37.77%
Understand	21M	46.66%
Apply	0M	0%
Analyze	02M	0.044%
Evaluate	05M	11.11%
Create	0M	0%
TOTAL	45M	100%



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INDUSTRIAL PHARMACY-II VII Semester B Pharm

Long Essays-10Marks

1. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.
Write a note on WHO guidelines for Technology Transfer (TT).
2. Discuss Regulatory requirement of NDA approval process.
3. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.
4. Explain the significance of documentation in BA-BE studies and add a note on outsourcing BA and BE to CRO.
5. Explain how master formula records and batch manufacturing records are developed in pilot plant scale up studies.
6. Discuss the Role of Regulatory affairs department in pharma industry.
7. Explain the protocol for pilot plant scale up for tablets production.
Discuss the Granularity of TT Process for Active Pharmaceutical Ingredients (API) and excipients.
8. What are the data's to be submitted during New Drug Application (NDA) filing
9. Explain the requirements for pilot plant scale up of Liquid Orals.
What are the contents of Technology transfer protocol?
10. Explain the Different Phases of drug development.
11. Explain the requirements for pilot plant scale up of Semisolids.
12. Explain the functioning of various Drug Development Teams.
13. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.
14. Describe in detail the process of Investigational New Drug Application.
15. Give Regulatory Requirements for INDA approval process.
Explain the concepts of Total Quality Management and Quality by Design (QbD).
16. Explain the CDSCO and COPP.



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17. Explain in detail Pilot plant scale up considerations for Liquid orals. Write a note on platform technology.
What is technology transfer? Discuss the TT protocol, process, packaging and cleaning.
18. Discuss regulatory requirement of NDA approval process, modules of CTD.
19. Write a note on platform technology.
Name the various Approved regulatory bodies and agencies in TT. Explain any two.
20. Explain in detail the process of transfer from R and D to Production.

Short Essays -5Marks

1. Write a note on Platform Technology.
2. Write a note on Technology transfer proto
3. Explain the responsibilities of regulatory affairs professionals.
4. Explain six sigma concepts for Quality Improvement.
5. Define TQM? Discuss in detail the principles of TQM.
6. What is CDSCO? What are the different functions of CDSCO?
7. Explain the requirements for pilot plant scale up of Liquid Orals.
What are the different reasons of Technology Transfer?
8. Discuss Granularity of TT Process for API.
9. Write a note on investigators brochure.
10. Write a note on QbD concept as per ICH Q8 Guidelines.
11. Discuss the objectives and scope of GLP in Pharmaceutical industry.
12. Discuss how OSS results are handled in pharmaceutical industry.
13. Explain in detail certification of pharmaceutical product.
14. What is a pilot plant? What is the significance of Pilot Plant scale up techniques?
15. Discuss the TT Process of packaging materials.
16. Describe the key elements in managing clinical programs.
17. What are the advantages of Implementing TQM.
18. What are the Benefits of NABL accreditations?
19. Write a note on Central Drugs Testing Laboratories (CDTL).
20. Describe the Organization of CDSCO with flow diagram.
21. Discuss the Significance of personnel requirements in pilot Plant scale up.
Discuss the Documentation process involved in TT.
22. Discuss the Types of studies involved in Pre-clinical Drug Development.
23. Write a note on ICH E6 (R2) Good Clinical Practice guidelines.
24. Write a note on QbD concept as per ICH Q8 Guidelines.
25. Write a note ISO 14000 Guidelines.
26. Write a note on Drug Technical Advisory Board (DTAB) and its functions.
27. Write a note on Drug Approval of New Drugs in India.
28. Discuss the space requirements in pilot Plant scale up.



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29. What are the various steps involved in Transfer of analytical methods.
What are the Contents of the Investigator's Brochure?
30. Explain the Responsibility of the Regulatory Affairs Professionals.
31. What are the conditions under which laboratories can be disqualified according to GLP?
32. Explain the procedure of NABL accreditation.
33. Describe the WHO Certification Scheme for a Certificate of Pharmaceutical Product (COPP).
34. Functions of State Drug Regulatory Authorities (SDRAs).
35. Define clinical trials? Why are the clinical trials required?
36. List out Risk management methodology and What are the Equipment requirements during TT?
37. Discuss the Scope and objectives of Regulatory Affairs.
38. What does ICH stands for? Describe the composition of ICH.
39. Discuss the approval and implementation of Change control management System in Pharmaceutical Industry.
40. Write the Functions of Drugs Controller General of India (DCGI).
41. Describe the Process to apply for a COPP.
42. Discuss change in Equipment and process as per SUPAC Guidelines
43. Organization of technology transfer
44. Applications of Biostatistics in Pharmaceutical Product Development.
45. Explain the concepts of six sigma for Quality Improvement.
46. Explain briefly the protocol for conducting Non-clinical lab studies.
47. Describe the Types of COPP and Contents.
48. Describe the Organization of CDSCO with flow diagram.
49. Write a note on scale up process approval changes
50. Discuss the Technology Transfer agencies in India and Explain the significance of documentation in BA – BE studies.
51. Write in detail about Pilot plant scale up considerations for solids.
52. Write a note on documentation of finished products, packaging materials.
53. What is clinical research protocols and data presentation?
54. Write the elements of ISO14000.
55. Discuss the GLP and discuss the same.
56. Write about USFDA guideline for Good laboratory Practices.
57. Write a note on different phases of Clinical trials.
58. Write a note on Total quality management and Quality by design.
59. Discuss the SUPAC guidelines.
60. Explain briefly the handling of out of specification (OOS).
61. Write a note on Certificate of Pharmaceutical Product.
62. Define Documentation, APCTD, FDA, CTD and QbD.
63. Write the general considerations of Pilot plant.



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64. Write a note SUPAC Guidelines and List out the responsibilities of Sending Unit in technology transfer.
65. What are information's required in Process Technology Transfer.
66. Explain Investigator's Brochure.
67. Write a note on different philosophies of TQM.
68. Explain the steps involved in ISO 9000 registration.
69. How to obtain COPP.
70. Write a note on Drug Approval of New Drugs in India.

Short Answer-2Marks

1. What is master formula records?
2. Write the principles of quality risk management.
3. Enumerate the objectives of TIFAC.
4. Name the different types of drug applications that can be submitted to FDA.
5. What are the objectives of ICH guidelines?
6. What are the benefits of ISO 9000?
7. List out the significance of NABL accreditation
8. Define medical device. Give two examples.
9. Give two applications of biostatistics in pharmaceutical product development.
10. How equipment's are categorized as per SUPAC guideline.
11. What are the significance pilot plant?
12. Differentiate qualification and calibration of equipment.
13. Write the primary functions of APCTD.
14. What is the purpose of confidential agreement?
15. What are the advantages of implementing TQM.
16. Mention the advantages of QbD.
17. Define clinical trials and write its importance.
18. Define biostatistics.
19. What are the objectives of OOS.
20. Name the technology transfer agencies in India.
21. Enlist the significances of batch formula record.
22. How equipment are categorized as per SUPAC guideline
23. Write the two importance of Technology Transfer in Pharmaceutical Industry.
24. Write the primary objectives NRDC.
25. Write two key elements in managing clinical programs.
26. Write the significance BE study.
27. What is zero-defect product?
28. What are the objectives of GLP.
29. Two functions of Port Offices of CDSCO



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30. Write the types of drugs for which COPPs may be issued.
31. What are the different parts of batch manufacturing record?
32. What is platform technology?
33. Write the two reasons for technology transfer in Pharmaceutical Industry.
34. Write the functions of BCIL.
35. List out various Regulatory Authorities.
36. Name the two key elements in managing clinical programs.
37. Write the four reasons for disqualification of testing facilities.
38. Classify Changes and give examples.
39. What is CTD.
40. Difference between assignable and non-assignable causes as per OOS.
41. Significance of Raw material requirements.
42. Write the benefits of pilot plant scale up studies
43. Write the two reasons for technology transfer in Pharmaceutical Industry.
44. Write the two functions of TIFAC.
45. Name the two significance of New Drug Application (NDA).
46. List the two key responsibilities of Regulatory Affairs.
47. What are the elements of QbD.
48. Classify Changes and give examples.
49. What are the significances of CTD?
50. What are the Types of COPP.
51. Name the contents of batch manufacturing record.
52. Name any four general requirements for pilot plant construction
53. What are the Steps involved technology transfer
54. Write features of TBSE.
55. Write the two significances of BE Study.
56. What is ADR reporting
57. Define TQM? What are the key elements of TQM.
58. Enlist the benefits of ISO 14000.
59. List out places of Zonal offices and Sub-zonal offices of CDSO.
60. What is the scope of COPP.
61. Write the benefits of pilot plant scale up studies
62. Name any four general requirements for pilot plant construction
63. Enlist the significances of batch formula record
64. Write the primary objectives of NRDC.
65. Write the two reasons for technology transfer in Pharmaceutical Industry.
66. Define validation and qualification.
67. Name types of studies involved in Pre-clinical Drug Development.
68. Name the five ICH efficacy guidelines with number and title.
69. What are the personnel requirements as per GLP.



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70. What is zero-defect product?
71. Write the significance of personnel requirements.
72. Write the guidelines for technology transfer (TT).
73. Write the functions of clinical studies.
74. What is State licensing authority?
75. What are the objectives of NRDC.
76. What are MoUs and legal issues?
77. Define qualification and validation.
78. Discuss the Role of Regulatory affairs department.
79. What is six sigma concept and OOS.
80. Salient features of ISO 9000.
81. Elements of TQM.
82. Define clinical research protocol.
83. What is innovation and collaboration?
84. Quality control in Technology transfer.
85. What is CMC and preclinical testing?
86. Prospective validation.
87. Detection limit and Quantitation limit.
88. What is investigators brochure.
89. Write about similarity factors and its significance.
90. Write the principles of total quality management.
91. Write the primary objectives of pilot plant.
92. Enlist the significances of batch formula record.
93. Write two responsibilities the Receiving Unit in technology transfer
94. What are the legal issues in TT.
95. Write two functions of Drug Development Team.
96. Define Bioavailability and bioequivalence.
97. Write two objectives of GLP.
98. Define standard deviation.
99. Write two advantages of the COPP scheme.
100. Write two functions of State Drug Regulatory Authorities (SDRAs)



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Code: BP702T

R19

B.Pharm IV Year I Semester (R19) Regular Examinations January 2023

INDUSTRIAL PHARMACY - II

Time: 3 hours

Max. Marks: 75

PART – A (Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- | | |
|---|----|
| (a) Define pilot and scale up. | 2M |
| (b) Give the objectives of pilot plants. | 2M |
| (c) Define Drug Master File (DMF) | 2M |
| (d) What do you mean by analytical method transfer. | 2M |
| (e) Mention the major regulatory bodies in the world. | 2M |
| (f) Define clinical trial protocol. | 2M |
| (g) Give the purposes of ICH guidelines. | 2M |
| (h) Write about ISO 9000 series. | 2M |
| (i) Write the functions of RDTL. | 2M |
| (j) Where the office of CDL & CDSCO is located. | 2M |

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

- | | | |
|---|--|-----|
| 2 | Discuss in details the pilot plant scale up consideration for solid dosage form. | 10M |
| 3 | (a) Discuss technology transfer from R & D to production as per WHO guidelines. | 6M |
| | (b) Describe in short about qualification and validation for TT as per WHO guidelines. | 4M |
| 4 | Explain regulatory requirement approval for obtaining NDA. | 10M |

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

- | | | |
|----|---|----|
| 5 | (a) What is SUPAC means? | 1M |
| | (b) Enlist the SUPAC guidelines. | 4M |
| 6 | (a) Define platform technology. | 2M |
| | (b) Give its applications. | 3M |
| 7 | (a) Explain IQ, DQ, OQ and PQ. | 4M |
| | (b) Define GMP as per WHO guidelines. | 1M |
| 8 | Discuss about premises and equipments for TT as per WHO guidelines. | 5M |
| 9 | Discuss the different phases of clinical trial. | 5M |
| 10 | (a) Define regulatory affairs. | 1M |
| | (b) Discuss the role and responsibilities of RA professional. | 4M |
| 11 | (a) Explain QbD. | 3M |
| | (b) Give its applications. | 2M |
| 12 | Write a note on six sigma concept. | 5M |
| 13 | Write about the functions of state regulatory authority. | 5M |



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B.PHARMACY – III-YEAR-II-SEM (VI SEM)-2023-2024 (R19)

MID EXAMINATIONS AVERAGE MARKS AWARD LIST

Name of the Sub: IP-II Sub. Code:BP705T

(Theory)

Lab code:

Sl No.	H.T.No	Name Of The Student	MID-I		MID-II		Avg (15M)	Continuous Mode (10 M)	Total (25M)
			FOR 30 M	FOR 15 M	FOR 30 M	FOR 15 M			
1.	21T11R0001	Ajay Kumar Madiga	26	13	26	13	13	8	21
2.	21T11R0002	Ajaykumar Sanipiralla	22	11	26	13	12	8	20
3.	21T11R0003	Akhila Sejala	26	13	26	13	13	8	21
4.	21T11R0004	Akhila Uppara	26	13	29	15	14	9	23
5.	21T11R0005	Anusha Chennavaram	24	12	28	14	13	8	21
6.	21T11R0006	Arju Chalam	24	12	28	14	13	8	21
7.	21T11R0007	Arshiya Dafedar	24	12	26	13	13	8	21
8.	21T11R0008	Bharath Rao Sindhe	24	12	24	12	12	8	20
9.	21T11R0009	Bhargav Dandina	26	13	26	13	13	8	21
10.	21T11R0010	Bhargavi Gorakappa Gari	26	13	26	13	13	8	21
11.	21T11R0011	Bhavana Malarapu	25	12.5	28	14	13	8	21
12.	21T11R0012	Bhavana Vuruvakili	28	14	28	14	14	9	23
13.	21T11R0013	Bhavani Derangi	29	14.5	28	14	14	9	23
14.	21T11R0014	Bhumika Yerikala	26	13	26	13	13	8	21



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15.	21T11R0015	Chaithra K	24	12	28	14	13	8	21
16.	21T11R0016	Chintu Naik R	26	13	28	14	14	9	23
17.	21T11R0017	Deepika Rani Siraalla	25	12.5	28	14	13	8	21
18.	21T11R0018	Deekshitha N	26	13	28	14	14	8	22
19.	21T11R0019	Deepthi G K	NA	NA	NA	NA	NA	NA	13
20.	21T11R0020	Divya Mala Basam	24	12	26	13	13	8	21
21.	21T11R0021	Divyasree Bachu	28	14	28	14	14	9	23
22.	21T11R0022	Fouziya Kattubadi	26	13	28	14	14	9	23
23.	21T11R0023	Gagana S J	29	14.5	29	14.5	14	10	24
24.	21T11R0024	Ganesh Boya	26	13	26	13	13	8	21
25.	21T11R0025	Geethika Karnam	NA	NA	NA	NA	NA	NA	14
26.	21T11R0026	Gousia Shaik	25	12.5	28	14	13	8	21
27.	21T11R0027	Gousiya Banu Benki	26	13	28	14	14	9	23
28.	21T11R0028	Gowthami K S	NA	NA	NA	NA	NA	NA	13
29.	21T11R0029	Hafijabee Syed	NA	NA	NA	NA	NA	NA	13
30.	21T11R0030	Hajira Khanam N	26	13	26	13	13	8	21
31.	21T11R0031	Harika Bachu	26	13	28	14	14	9	23
32.	21T11R0032	Harshini Islapuram	28	14	13	15	15	10	24
33.	21T11R0033	Hijiya Bee Gagguturu	26	13	26	13	13	8	21
34.	21T11R0034	Indira Racherla	26	13	26	13	13	8	21
35.	21T11R0035	Indu Pommala	26	13	24	12	13	8	21



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36.	21T11R0036	Jaithrasai Gaddam	22	11	24	12	12	8	20
37.	21T11R0037	Jayasree Palem	27	13.5	28	14	14	9	23
38.	21T11R0038	Jeevan Reddy Kona	26	13	24	14	14	9	23
39.	21T11R0039	Jnana Sai P	25	13	26	13	13	8	21
40.	21T11R0040	Kamalnath Reddy Gundra	24	12	22	11	12	8	20
41.	21T11R0041	Kavya Sri Janagana	26	13	26	13	13	8	21
42.	21T11R0042	Keerthana Bokki	28	14	26	13	14	9	23
43.	21T11R0043	Keerthi Godditi	26	13	28	14	14	8	23
44.	21T11R0044	Keerthi Jinkala	27	14	28	14	14	9	23
45.	21T11R0045	Kishore Babu C	27	14	28	14	14	9	23
46.	21T11R0046	Kushiya Dudekula	26	13	28	14	14	9	23
47.	21T11R0047	Lakshmi Kammara	28	14	28	14	14	9	23
48.	21T11R0048	Lakshmilatha K A	28	14	30	15	15	10	24
49.	21T11R0049	Leelavathi Chinthakayala	26	13	24	12	13	8	21
50.	21T11R0050	Mahalakshmi Urapasula	28	14	28	14	14	9	23
51.	21T11R0051	Mahammad Thosif Mitaigari	26	13	26	13	13	8	21
52.	21T11R0052	Manjulatha Boppi	29	15	29	14.5	15	10	24
53.	21T11R0053	Meghana Ganta	29	15	29	14.5	15	10	24
54.	21T11R0054	Md. Masood Shaik Bashas	24	12	26	13	13	8	21



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55.	21T11R0055	Mohammed Akram Shaik	NA	NA	NA	NA	NA	NA	13
56.	21T11R0056	Mohammed Sami Bar Shaik	24	12	26	13	13	8	21
57.	21T11R0057	Mubeen Taj Achukatla	24	12	26	13	13	8	21
58.	21T11R0058	Muzammil Khan Patan	26	13	26	13	13	8	21
59.	21T11R0059	Naga Sai Sahithi Kaipa	16	8	24	12	10	8	18
60.	21T11R0060	Nagarjuna Jetti	25	13	26	13	13	8	21
61.	21T11R0061	Naqeeba Banu Syeda	24	12	27	14	13	8	21
62.	21T11R0062	Narendra Golla	26	13	20	10	12	8	20
63.	21T11R0063	Naveen Kumar Mangala	25	13	28	14	14	9	23
64.	21T11R0064	Navya K	28	14	26	13	14	9	23
65.	21T11R0065	Neeha Duvvur	29	15	28	14	15	10	24
66.	21T11R0066	Neha Parvez Shaik	25	13	28	14	14	9	23
67.	21T11R0067	Nikhil Avinash Gurugundla	26	12	NA	NA	7	9	16
68.	21T11R0068	Noorjahan Khaji	28	14	28	14	14	9	23
69.	21T11R0069	Pallavi Thippanna Gari	28	14	26	13	14	9	23
70.	21T11R0070	Pavan Kumar Sake	NA	NA	NA	NA	NA	NA	13
71.	21T11R0071	Pavithra Mallireddy	26	13	26	13	13	8	21
72.	21T11R0072	Pedda Ezra PradeepDudekula	24	12	24	12	12	8	21



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73.	21T11R0073	Pranitha Gunivantla	26	13	28	14	14	9	23
74.	21T11R0074	Pujitha Mallepogula	29	15	28	14	15	10	24
75.	21T11R0075	Raju Naik Vadithya	24	12	27	13.5	13	8	21
76.	21T11R0076	Rakhiya Mehanoor Pathan	26	13	26	13	13	8	21
77.	21T11R0077	Ramya Sree G	26	13	28	14	14	9	23
78.	21T11R0078	Ramya Sree Ramavath	NA	NA	NA	NA	NA	NA	13
79.	21T11R0079	Ranjitha Bai Vadithya	27	14	28	14	14	9	23
80.	21T11R0080	Sadiq Hussain Sayed	26	13	28	14	14	9	23
81.	21T11R0081	Sai Charan B N	NA	NA	NA	NA	NA	NA	13
82.	21T11R0082	Sai Charan V N	26	13	26	13	13	8	21
83.	21T11R0083	Sai Nived Talari	24	12	28	14	13	8	21
84.	21T11R0084	Sai Vedamsh B R	21	11	26	13	12	8	20
85.	21T11R0085	Sailaja Kayapati	29	15	30	15	15	10	24
86.	21T11R0086	Sakheeb Shaik	24	12	26	13	13	8	21
87.	21T11R0087	Sameera Firdous Kolimi	26	13	27	13.5	13	8	21
88.	21T11R0088	Sandeep Bhushan Parsham	NA	NA	NA	NA	NA	NA	13
89.	21T11R0089	Sandhya Vanganooru	28	14	28	14	14	9	23
90.	21T11R0090	Sangeetha R	NA	NA	NA	NA	NA	NA	13
91.	21T11R0091	Sanjay Kumar Pappu	26	13	28	14	14	9	23
92.	21T11R0092	Santhosh Vaddi	NA	NA	NA	NA	NA	NA	13



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93.	21T11R0093	Sathish Kumar D	26	13	24	12	13	8	21
94.	21T11R0094	Sharanya Sai Amberker	26	13	24	12	13	8	21
95.	21T11R0095	Shiva Guvvala	NA	NA	NA	NA	NA	NA	13
96.	21T11R0096	Siddaraju T	NA	NA	NA	NA	NA	NA	13
97.	21T11R0097	Sree Lalitha N V	27	14	28	14	14	9	23
98.	21T11R0098	Sreeja R	27	14	28	14	14	9	23
99.	21T11R0099	Sunitha Bhavani Jalavadi	28	14	29	14.5	14	9	23
100.	21T11R00A0	Teerthini Kuruba	27	14	29	14.5	14	9	23
101.	21T11R00A1	Teja Kummari	26	13	28	14	14	9	23
102.	21T11R00A2	Trivikram Narepalli	29	15	28	14	15	10	24
103.	21T11R00A3	Vaishnavi Kodipalli	27	14	28	14	14	9	23
104.	21T11R00A4	Varsha B	26	13	28	14	14	9	23
105.	21T11R00A5	Vasantha Golla	26	13	28	14	14	9	23
106.	21T11R00A6	Vasanthi Kamatham	27	14	26	13	14	9	23
107.	21T11R00A7	Vijay Singepalli	26	13	26	13	13	8	21
108.	21T11R00A8	Vinila Karnatakam	26	13	26	13	13	8	21
109.	21T11R00A9	Yamini Guduru	24	12	22	11	12	8	20
110.	21T11R00B0	Aruna Vetti	NA	NA	NA	NA	NA	NA	13
111.	21Z71R0006	T. Bala krishna	26	13	26	13	13	8	21
112.	22T15R0001	A.Mehataz	26	13	26	13	13	8	21
113.	20GT1R0045	K.Tejaswini	21	11	26	13	12	8	20



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Signature of the faculty member