Academic Year 2024 – 2025

Class: III-II

Program: B. Pharm

Name of the Course: **PHARMACEUTICAL QUALITY ASSURANCE**

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.

File No.SCHE-JNTA/910/2024-JNTUA-EHE73

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

ACADEMIC CALENDAR 2024-25

B.Pharm III Year I & II Semesters

(for 2022 admitted batch)

Description	From To	No. of weeks/days
I Semester		
Commencement of Class work	**29.07.2024**	-
Instruction Period for the Semester	29.07.2024 to 23.11.2024	(17 weeks)
Examinations:		
I Mid-term Examinations	23.09.2024 to 25.09.2024	(03 Days)
II Mid-term Examinations	25.11.2024 to 27.11.2024	(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 III Year B.Pharm II semester	**23.12.2024 (Monday)**	
Declaration of results for III-I	**18.01.2025**	

II Semester		
Commencement of Class work	**23.12.2024**	-
Instruction Period for the Semester	23.12.2024 to 19.04.2025	(17 weeks)
Examinations:		
I Mid-term Examinations	17.02.2025 to 19.02.2025	(03 Days)
II Mid-term Examinations	17.04.2025 to 19.04.2025	(03 Days)
End laboratory Examinations:	21.04.2025 to 26.04.2025	(01 week)
End Theory Examinations:	28.04.2025 to 09.05.2025	(02 weeks)
Commencement of Short-Term Internship/Summer vacation	12.05.2025 to 12.07.2025	(02 Months)
Commencement of Class Work for IV Year B.Pharm I semester	**14.07.2025 (Monday)**	
Declaration of results for III-II	**02.06.2025**	

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.

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Date: 27-06-2024 13:12:48
Reason: Approved

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: 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 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 effectiveinterpersonal 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.

Course objectives

- This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.
- Upon completion of the course student shall be able to:
    - Understand the cGMP aspects in a pharmaceutical industry.
    - Appreciate the importance of documentation.
    - Understand the scope of quality certifications applicable to pharmaceutical industries.
    - Understand the responsibilities of QA & QC departments.

Course outcomes

S.No	Course Outcomes	Knowledge level (BLOOMS Level)
After successful completion of the course student shall be able to explain		
CO1:	Understand the aspects of quality assurance, total quality Management, ICH guidelines, QbD, relevant ISO and accreditation process in a pharmaceutical industry.	L1: Remember L2: Understand L3: Apply
CO2:	Describe the importance of organization, personnel, premises, equipment and raw material as per cGMP guideline.	L3: Apply L4: Analyse L5: Evaluate
CO3:	Explain the quality control and GLP practices followed in Pharmaceutical Industry.	L3: Apply L4: Analyse L5: Evaluate
CO4:	Appreciate the importance of documentation and complaint procedure.	L3: Apply L4: Analyse L5: Evaluate
CO5:	Apply the principles of calibration and validation and follow good warehousing practices	L3: Apply L4: Analyse L5: Evaluate

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

How program out comes 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)

Course Outcomes and Program Outcomes (CO-PO) Mapping:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1												
CO2												
CO3												
CO4												
CO5												
Avg												

Course Content

45 Hours

UNIT-I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools **ISO 9000 & ISO14000**: Overview, Benefits, Elements, steps for registration **NABL accreditation**: Principles and procedures

UNIT-II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipment and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT-III **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities.

UNIT-IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT-V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.

2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.

3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications.

4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh

5. How to Practice GMP's – P P Sharma.

6. ISO 9000 and Total QualityManagement – Sadhank G Ghosh

7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms

8. Good laboratory Practices – Marcel Deckker Series

9. ICH guidelines, ISO 9000 and 14000 guidelines

LESSONPLAN

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

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

Name of the Course: **PHARMACEUTICAL QUALITY ASSURANCE**

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

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

S.No	Chapter name	Topic	No. of hours	Name of the faculty
1	**UNIT 1**	Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP Total Quality Management (TQM): Definition, elements, philosophies ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation: Principles and procedures	**10**	**Dr. K V Lalitha Professor**
2.	**UNIT 2**	Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipment and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials	**10**	**Dr. K V Lalitha Professor**
3.	**UNIT 3**	Quality Control: Quality control test for containers, rubber closures and secondary packing materials. Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical	**10**	**Dr. K V Lalitha Professor**

		Laboratory Study, Records and Reports, Disqualification of Testing Facilities		
4.	**UNIT 4**	Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records	**8**	**Dr. K V Lalitha Professor**
5.	**UNIT 5**	Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. Warehousing: Good warehousing practice, materials management	**7**	**Dr. K V Lalitha Professor**

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

Name of the Course: **PHARMACEUTICAL QUALITY ASSURANCE**

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

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

ASSIGNMENTS

ASSIGNMENTTOPIC	Course Outcome	BTL
Assignment1		
Total Quality Management (TQM)	**C 405.1**	Remembering
Premises: Design, construction and plant layout	**C 405.2**	Applying
Assignment2		
Complaints and evaluation of complaints	**C 405.4**	Analyzing
Qualification of UV-Visible spectrophotometer	**C 405.5**	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.

Balaji College of Pharmacy, Ananthapuramu.

IV-Year II-sem B.Pharmacy

I Mid Examinations, FEB–2025

SUB: BP606T. PHARMACEUTICL QUALITY ASSURANCE

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

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

S.No	Question	Marks	Course Outcome	BTL
1.	Write about control articles in a lab as per GLP?	2M	CB606.3	Remembering
2.	Enlist Tests for Plastic containers?	2M	CB606.3	Analyzing
3.	What is ISO 14000?	2M	CB606.1	Remembering
4.	Write about Personnel Hygine maintanence in the Pharma Industry?	2M	CB606.2	Remembering
5.	What are Q_1 A(R_2) and Q_2(R_1)?	2M	CB606.1	Remembering

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

S.No	Question	Marks	Course Outcome	BTL
6.	(a) Describe about W-Edward Deming TQM Philosophies (b)Comment on the joint Responsibilities of QA and Production Head	10M	CB606.1 & CB606.2	Analyzing & Remembering
7.	(a) Write briefly on Organization and its Elements (b)Write the Elements of the QbD Program me	10M	C606.2 & CB606.1	Remembering & Evaluating

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

S.No	Question	Marks	Course Outcome	BTL
8.	Explain about the Facilities required in a lab according to GLP?	5M	CB606.3	Remembering
9.	Write about ICH Q -Series Guidelines?	5M	CB606.1	Understanding & Evaluating
10.	Write the sources of contamination and its prevention in Sterile area?	5M	CB606.2	Remembering & Understanding

Course Outcome analysis:

CO	Total CO Marks	%CO
CB606.1	19M	42%
CB606.2	17M	36%
CB606.3	09M	20%
CB606.4	0M	0%
CB606.5	0M	0%
TOTAL	45M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	Taxonomy Marks	%Taxonomy
Remember	25M	56%
Understand	10M	22%
Apply	0M	0%
Analyze	7M	16%
Evaluate	03M	6%
Create	0M	0%
TOTAL	45M	100%

Code No: **BP606T** Roll.No:

Balaji College of Pharmacy, Ananthapuramu.

IV-Year II-Sem B.Pharmacy

II-Mid Examinations, APRIL–2025

SUB: BP606T. PHARMACEUTICL QUALITY ASSURANCE

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

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

S.No	Question	Marks	Course Outcome	BTL
1.	Write the difference between Calibration and Validation.	2M	CB606.5	Remembering
2.	Define Pharmaceutical Process Validation?	2M	CB606.5	Analyzing
3.	What do you mean by product recalls?	2M	CB606.4	Remembering
4.	Write about the types of Complaints?	2M	CB606.4	Remembering
5.	What is the formula for LOQ and explain?	2M	CB606.5	Remembering

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

S.No	Question	Marks	Course Outcome	BTL
6.	(a) Describe the warehousing area of pharmaceutical manufacturing premises in brief b) Write a note on Master Formula Record	10M	CB606.5 & CB606.4	Analyzing & Remembering
7.	(a) Discuss the parameters for performance qualification of UV-Visible Spectrophotometer. (b)Explain about Validation Master Plan	10M	CB606.5	Remembering & Evaluating

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

S.No	Question	Marks	Course Outcome	BTL
8.	Explain about DQ and IQ	5M	CB606.5	Remembering
9.	Write about maintenance of Batch Formula Record in Pharmaceutical Industry	5M	CB606.4	Understanding & Evaluating
10.	What is Quality audit and write the comments on Quality audit	5M	CB606.4	Remembering & Understanding

Course Outcome analysis:

CO	Total CO Marks	%CO
CB606.1	0M	0%
CB606.2	0M	0%
CB606.3	0M	0%
CB606.4	19M	42%
CB606.5	26M	58%
TOTAL	45M	100%

Blooms taxonomy analysis for educational objectives:

Taxonomy	Taxonomy Marks	%Taxonomy
Remember	25M	56%
Understand	6M	13%
Apply	0M	0%
Analyze	07M	16%
Evaluate	07M	16%
Create	0M	0%
TOTAL	45M	100%

PHARMACEUTICAL QUALITY ASSURANCE (BP606T) - III B Pharm sem-2 Question bank

10 Marks Questions

1. Discuss in detail the design, construction, plant layout and requirement of environmental control in sterile manufacturing unit
2. Discuss the objectives and scope of GLP in Pharmaceutical industry
3. Discuss in detail the principles of TQM
4. Explain the facility requirements for maintenance of sterile manufacturing area
5. Discuss the importance of Good Laboratory Practices Explain briefly the protocol content of non-clinical laboratory study
6. List and explain Q series guidelines of ICH
7. Describe the requirements s of organization and personal responsibilities as per schedule M
8. Explain in detail the quality control test for packaging materials.
9. Explain ICH Q1 guidelines for stability testing of drug and drug product
10. Discuss briefly cGMP guidelines for construction, maintenance and sanitation of pharmaceutical unit
11. Explain the objectives and scope of GLP
12. Discuss the important principles of Total Quality Management
13. Describe the requirements for environmental control and layout of sterile manufacturing area
14. Explain the objectives and scope of GLP
15. Describe in-detail the features of ISO 9000 and ISO 14000.
16. Discuss the regulatory requirements for design, construction and plant layout of pharmaceutical manufacturing facility
17. Explain the quality control tests for containers used in pharmaceutical packaging
18. Discuss in detail about the concepts of Quality Assurance and GMP
19. Explain about the quality control tests for containers and rubber closures
20. Describe the design, construction and plant layout of a production unit
21. Explain scope and objectives of GLP.
22. Write in detail about personnel responsibilities, training and hygiene in pharmaceutical industry.
23. Write in detail about NABL accreditation, principles and procedures.
24. Give a detail account on stability testing of dosage form as per the ICH guidelines
25. Discuss in-detail the salient features of Schedule-M
26. Explain the objectives and scope of GLP
27. What is QSEM and discuss in details Q-series guidelines
28. Discuss in detail the design, construction, plant layout and requirement of environmental control in sterile manufacturing

5 Marks Questions

1. Explain the steps involved in ISO 9000 registration
2. What is CTD and explain module -2
3. Write the significance of personnel hygiene in pharmaceutical industry
4. Describe the equipment selection and purchase procedure
5. Explain the protocol for conduct of non-clinical laboratory study
6. Explain the quality control tests for containers and rubber closures
7. Discuss the handling of return goods
8. Explain the importance and scope of validation
9. Explain the concept of QA and QC
10. Enlist ICH Q-series guidelines and explain any one in detail
11. Describe the criteria for equipment selection in pharmaceutical industry
12. How is cross contamination is prevented in dispensing unit
13. Write the reasons for disqualification of testing facilities
14. Describe the procedure for handling of return goods
15. Write a short note on quality audit and quality review
16. Explain the procedure for qualification of pH meter
17. Describe the principle of analytical method validation
18. Explain the principles are of TQM
19. Explain the scope and features of NABL accreditation
20. Discuss the steps involved in the purchase specification.
21. Write a note on maintenance of stores for raw materials
22. Give reasons for disqualification of testing facilities in GLP
23. Explain briefly the protocol for conducting non-clinical lab studies
24. What are complaints and how they are evaluated?
25. How do you handle disposal of waste products in pharmaceutical unit.
26. Write the procedure for qualification of UV- Visible spectrophotometer
27. Write the elements of ISO 9000
28. Write the procedure for NABL accreditation
29. How is the cross contamination prevented in dispensing and production areas.
30. How do you audit vendor for ensuring purchase specification
31. Discuss the procedure for conducting non clinical laboratory studies.
32. Discuss the SOP for disposal of waste in pharmaceutical unit.
33. Elaborate on master formula record
34. Write the procedurefor qualification of UV- Visible spectrophotometer
35. Write a note on ISO 9000 and ISO 14000
36. Explain briefly about ICH stability testing
37. Discuss the maintenance of raw material stores
38. Describe the SOP for purchase specification
39. Explain the procedure for qualification of UV visible spectrophotometer

40. Write a note on material Management
41. Discuss the QC tests for secondary packing materials
42. Explain briefly CTD and its modules
43. Explain the handling of market complaints
44. Explain the elements of QbD
45. Describe the methods to prevent product contamination in sterile manufacturing unit
46. Write the minimum criteria for selection of pharmaceutical equipments
47. Explain the procedure for NABL accreditation
48. Discuss the SOP for Handling of return goods
49. Explain the guidelines to be followed for waste disposal in pharmaceutical industry
50. Write in brief the material management in industry
51. Describe the protocol for conduct of non-clinical laboratory study
52. Enlist the reasons for disqualification of testing facility
53. Discuss the tools and elements of QbD program
54. Explain the protocol for conduct of non- clinical laboratory study
55. Write a note on NABL Accreditation
56. Describe briefly regarding equipment selection and purchase specification
57. Write briefly about Master Formula Record
58. Describe the maintenance of sterile area facilities
59. Write a note on good ware house practices
60. What is DMF and explain its contents
61. Summarize the reasons for disqualification of testing facility
62. Write in brief on processing of pharmaceutical complaints.
63. Explain the elements of TQM
64. What are the steps involved in validation?

2 Marks Questions

1. What are the benefits of ISO 9000?
2. What are the elements of QbD
3. Enlist the objectives of ICH
4. State the importance of personal records in manufacturing
5. Differentiate between validation and calibration
6. Explain secondary packing material
7. Write the importance of SOP in manufacturing
8. Enlist the significances of batch formula record
9. What the general principles of validation
10. Define accuracy and precision
11. Define QbD
12. Enlist the benefits of ISO 14000
13. Name any four Deming's principles of quality management

14. What are the steps involved in the purchase of raw materials
15. What are the personnel requirements as per GLP
16. Explain the role of SOP in manufacturing unit
17. What is Master formula record
18. What is FIFO and LIFO
19. Name any two parameters for qualification of UV-visible spectrophotometer
20. Write the importance of calibration
21. Write the difference between QA and QC
22. What are the benefits of QbD
23. Write a note on personal hygiene in pharmaceutical unit
24. Name different types of containers used in pharmaceutical industries
25. What is DMF and give its importance.
26. What is quality audit and quality review
27. Write the difference between qualification and validation
28. Explain the concept of FIFO
29. Write the difference between prospective and retrospective validation
30. Write the objective of ISO14000
31. Write any four elements of TQM
32. Define QA and QC
33. What is cross contamination and mix up contamination
34. Name any four types of closures
35. What is DMF? Give its importance
36. What is quality audit and quality review
37. Define calibration, qualification and validation
38. Write briefly the scope of validation.
39. Name the parameters used for analytical method validation.
40. What is the difference between QMS and EMS.
41. Define TQM
42. What are the materials used for secondary packaging?
43. Differentiate calibration and qualification
44. Define MFR
45. What are the objectives of validation
46. Write about quality documentation
47. What are the personal responsibilities in plant layout
48. Enlist Q series of ICH guidelines
49. Define NABL accreditation
50. Name different types of validation
51. What is Batch formula record?
52. Define Qualification and validation
53. Differentiate between quality control and Quality assurance
54. What are secondary packaging materials? Give examples

55. Define TQM
56. Differentiate QMS and EMS
57. Define is BMR and BPR
58. Write the importance of quality documentation
59. Name any four parameters for validation of analytical method
60. What is the significance of calibration
61. What is the difference between Quality Assurance and Quality control
62. Define standard operation procedure (SOP)
63. What is BMR
64. Define calibration and validation
65. Mention the elements of ISO 9000
66. Define QbD
67. What is contamination and cross contamination
68. Define Validation Master Plan.
69. What are secondary packing materials give example.
70. Define accuracy and precision.
71. What is batch formula record?
72. Define calibration.
73. Give the importance of Quality control.
74. What is ISO 14000?
75. Define ICH guidelines
76. What is secondary packing materials? Give two examples.
77. What is Quality review?
78. What is 'Recall' in pharmaceutical industry?
79. What are types of qualifications?
80. Define Validation.
81. What is quality assurance and TQM?
82. Define quality assurance and quality control
83. What is contamination and cross contamination
84. Differentiate ISO 9000 and ISO 14000
85. What is CTD
86. Define and classify containers
87. Differentiate calibration and qualification
88. Write the importance of SOP
89. What is LIFO and FIFO
90. Enlist the merits of warehousing
91. What are the benefits of ISO 9000?
92. What are the elements of QBD
93. Enlist the objectives of ICH
94. State the importance of personal records in manufacturing
95. Describe the design of sterile manufacturing

96. Explain secondary packing material
97. Write the importance of SOP in manufacturing
98. Enlist the significances of batch formula record

BALAJI COLLEGE OF PHARMACY: ANANTAPUR
B.PHARMACY – III-YEAR-II-SEM-2022-2023(R19)
THEORY MID EXAMINATIONS AVERAGE MARKS AWARD LIST
Name of the Sub: PHARMACEUITCAL QUALITY ASSURANCE Sub. Code: BP606T

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	22T11R0001	Abhi Ravi Gari	24	12	26.5	13.5	13	7	20
2	22T11R0002	Aditya Dasa	26	13	27	13.5	14	8	22
3	22T11R0003	Afreen Taj K S	27	13.5	27.5	14	14	9	23
4	22T11R0004	Ajay Kumar Chakali							
5	22T11R0005	Aliya Tabassum L S	27	13.5	26.5	13.5	14	9	23
6	22T11R0006	Anitha Kunchapu	27	13.5	27	13.5	13.5	8	22
7	22T11R0007	Anitha Narappala	25.5	13	24	12	12.5	7	20
8	22T11R0008	Anjulatha Kondagogula							
9	22T11R0009	Anuradha P H	26	13	26.5	13.5	14	9	23
10	22T11R0010	Arjun Uppara	26	13	26	13	13	9	22
11	22T11R0011	Arshiya Banu C	27.5	14	28	14	14	8	22
12	22T11R0012	Atiya Khanam Mohammad	25.5	13	28	14	14	9	23
13	22T11R0013	Avinash Sajjanagandla	26	13	28	14	14	9	23
14	22T11R0014	Bhavana Kodathala	25	12.5	29	14.5	14	9	23
15	22T11R0015	Bhavya Spandana Pulla	27.5	14	29	14.5	14.5	10	23
16	22T11R0016	Bhavya Sree C	27	13.5	28	14	14	9	23
17	22T11R0017	Bheemeswari Kondapuram	27	13.5	26	13	14	8	22
18	22T11R0018	Bhumika Chakali	25	12.5	23	11.5	12	8	20
19	22T11R0019	Chandana Bandeeppagari	27	13.5	28	14	14	9	23
20	22T11R0020	Deepika Varikuti	26.5	13.5	27	13.5	14	8	22
21	22T11R0021	Dhanusha Prodduturu	26	13	27	13.5	14	9	23

22	22T11R0022	Dinesh Kumar Manchala	26	13	28	14	14	9	23
23	22T11R0023	Divya Bayamutaka	27.5	14	26.5	13	14	9	23
24	22T11R0024	Divya Sree Charugundla	26	13	26.5	13	13	9	22
25	22T11R0025	Faseeha Shaik	28	14	28	14	14	9	23
26	22T11R0026	Gnapika Pendem	26.5	13.5	28	14	14	9	23
27	22T11R0027	Gowri Muguda	24.5	12.5	26.5	13.5	13	10	23
28	22T11R0028	Harathi Valipi	26.5	13.5	26	13	13	9	22
29	22T11R0029	Hemanth Kumar Indla							
30	22T11R0030	Jagan Mohan Naik Bhukya	26.5	13.5	26	13	13	7	20
31	22T11R0031	Jahnavi Bestha							
32	22T11R0032	Jaswanth Reddy Reddyvari							
33	22T11R0033	Jayalakshmi Shivanna Gari	26	13	27	13.5	13	9	22
34	22T11R0034	Jyothsna Moola	25.5	13	26	13	13	9	22
35	22T11R0035	Kalpana Puttha	26.5	13.5	26.5	13.5	14	9	23
36	22T11R0036	Kranthi Yeggidi	26.5	13.5	27.5	14	14	8	22
37	22T11R0037	Krishna Veni G	26	13	22.5	11	12	9	21
38	22T11R0038	Kulsum Patan	27.5	14	27.5	14	14	6	20
39	22T11R0039	Lakshmi Korrapati	27.5	14	26	13	14	9	23
40	22T11R0040	Lakshmipriya Belle	26	13	26	13	13	9	22
41	22T11R0041	Lalitha Digivindla Chakala	26.5	13.5	27	13.5	13	9	22
42	22T11R0042	Likhitha Alugunti	27	13.5	26.5	13	13	8	21
43	22T11R0043	Madhu Pikkili							
44	22T11R0044	Mahammad Shakeer Gosaripalli	26	13	27	14	14	9	23
45	22T11R0045	Mahesh Khamithkar	26	13	28	14	14	9	23
46	22T11R0046	Manoj Kumar Avvari	25	12.5	26.5	13	13	8	21
47	22T11R0047	Meghamala Ventrukulappa Gari	26.5	13.5	27	13.5	13	9	22
48	22T11R0048	Meghana Jangam	25.5	13	27	13.5	13	7	20
49	22T11R0049	Mohammed Kaif N	21	11	24	12	12	9	21
50	22T11R0050	Mounika Chinna Gowni	27	13.5	27	13.5	14	9	23

51	22T11R0051	Mounika Goddumuri	26.5	13.5	27	13.5	14	9	23
52	22T11R0052	Muskan Silar	27.5	14	27	13	14	9	23
53	22T11R0053	Nagarjuna Thummasi	25	12.5	26	13	13	7	20
54	22T11R0054	Nageswari Bayappagari	24	12	26	13	13	8	21
55	22T11R0055	Nandini Ediga	27	13.5	26	13	14	9	23
56	22T11R0056	Nandini Sake	21.5	11.5	26	13	13	6	20
57	22T11R0057	Navaneetha Sunkara	27	13.5	27.5	14	14	9	23
58	22T11R0058	Navanitha Ponthati	29	14.5	27.5	13.5	14	8	22
59	22T11R0059	Naveen Raju Chakali	21.5	11.5	25.5	12.5	12	6	18
60	22T11R0060	Navya Muktham	28	14	26.5	13	14	8	22
61	22T11R0061	Navya Nandini Matam	26.5	13.5	26.5	13.5	14	8	22
62	22T11R0062	Nikhila Thalari	15	7.5	26	13	11	8	20
63	22T11R0063	Pallavi Beldon	28	14	27	13.5	14	7	20
64	22T11R0064	Pallavi Jasthi	25.5	13	27.5	13.5	13	8	21
65	22T11R0065	Pallavi Nagadani	27.5	14				9	
66	22T11R0066	Peddi Reddy Guda	24.5	13	26	13	13	8	21
67	22T11R0067	Prasanthi Kathe	23.5	12.5	27	14	14	7	21
68	22T11R0068	Pravallika Neeruganti	27	13.5	27	13.5	14	8	22
69	22T11R0069	Priyanka I	16.5	9	25.5	13	11	8	19
70	22T11R0070	Reena Vade Muthana	27	13.5	27.5	13.5	14	8	22
71	22T11R0071	Rozina Tabassum Dilkush							
72	22T11R0072	Rukmini Paruchuri	28	14	27.5	14	14	8	22
73	22T11R0073	Rupaamrutha Rallacheni	27	13.5	26.5	13.25	13.5	8	22
74	22T11R0074	Sabiha Thaslim Haji Achula							
75	22T11R0075	Sadikha Shaik	27	13.5	27.5	14	14	8	22
76	22T11R0076	Sahitha Neeruganti	23	12	26	13	13	7	20
77	22T11R0077	Sai Mounika Chinthamanu	28	14	28	14	14	8	22
78	22T11R0078	Sai Mukthi Malyavantham	26.5	13.5	26	13	13	9	22
79	22T11R0079	Samanthakamani Velpula	23	12	26	13	13	9	22

80	22T11R0080	Samarasimha Valmiki	27	13.5	26	13	13	9	22
81	22T11R0081	Sangeetha Dasari	28	14	28	14	14	8	22
82	22T11R0082	Saniya Ruhi Shaik	24	12	28	14	13	8	21
83	22T11R0083	Shahin Begum T M	24	12				7	
84	22T11R0084	Shahira Alisher	26	13	26	13	13	7	20
85	22T11R0085	Shamiulla Shaik	27	13.5	27	13.5	13.5	9	22
86	22T11R0086	Shilpa K A	25.5	12.5	26	13	13	9	22
87	22T11R0087	Shirisha Billa	27	13.5	23	11.5	12.5	9	21
88	22T11R0088	Shiva Sai Boggula	26	13	26.5	13.25	13	7	20
89	22T11R0089	Siddesh Yanjarappa Gari	25	12.5	26	13	13	7	20
90	22T11R0090	Simhadri Nallolla	24	12	26	13	12.5	7	20
91	22T11R0091	Sireesha Kamsala	20.5	11	25	12.5	12	8	20
92	22T11R0092	Snehalatha Talari	26.5	13.5	28	14	14	8	22
93	22T11R0093	Soundarya Rajappagari	26.5	13.5	26	13	13	8	21
94	22T11R0094	Sravani Siriyapu Reddy	27	13.5	26.5	13.25	13.5	8	22
95	22T11R0095	Sri Lakshmi Kurupati	25.5	12.5	27	13.5	13	9	22
96	22T11R0096	Suchitra Sagabala	25	12.5	26	13	13	9	22
97	22T11R0097	Sumalatha Yerasi	28	14	26	13	13.5	8	22
98	22T11R0098	Suneetha Kappala	27	13.5	25	12.5	13	8	21
99	22T11R0099	Swetha Neelam	24	12	27	13.5	13	8	21
100	22T11R00A1	Tanuja Busetty	27	13.5	26.5	13.25	13.5	9	22
101	22T11R00A2	Tejasri Challa	27.5	14	27	13.5	14	9	23
102	22T11R00A3	Tejaswini T	27	13.5	26	13.25	13.5	8	22
103	22T11R00A4	Uma Maheswara S Manikanta S	14	7	22	11	9	7	16
104	22T11R00A5	Vasanthi Bandi	24.5	13	26	13	13	8	21
105	22T11R00A6	Vasundara Vadde	26	13	27	13.5	13	8	21
106	22T11R00A7	Venkat Nikheyth Reddi C	20.5	11	20	10	10	6	16
107	22T11R00A8	Vishala Jenne	28	14	28	14	14	9	23
108	22T11R00A9	Vishnuvardhan Reddy Lingala	26	13	27	13.5	13	8	21
109	22T11R00B0	Yogananda N	24	12	26	13	12.5	7	20
110	23T15R0001	Anjali A	26.5	13.5	28	14	14	8	22
111	21KM1R0015	Mani kumar T						7	
112	219N1R0071	Haritha T	28	14	28	14	14	8	22

R19

Code: BP606T

B.Pharm III Year II Semester (R19) Regular & Supplementary Examinations May 2025
QUALITY ASSURANCE
(B.Pharmacy)

Time: 3 hours Max. Marks: 75

PART – A
(Compulsory Question)
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1 Answer the following: (10 X 02 = 20 Marks)

(a)	State the purpose of ICH guidelines.	2M
(b)	What is QSEM?	2M
(c)	Write about the purchase specification.	2M
(d)	Enlist the sources of contamination and explain how cross contamination can be controlled.	2M
(e)	Name the evaluation tests for plastic containers and explain about any one test.	2M
(f)	Explain shortly disqualification of testing facilities.	2M
(g)	Define quality review.	2M
(h)	Write about distribution records.	2M
(i)	Define retrospective validation.	2M
(j)	Classify different types of audit.	2M

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

2	(a)	How a pH meter will be calibrated?	5M
	(b)	Discuss the steps involved in the validation master plan.	5M
3		Describe the principles and procedures for NABL accreditation.	10M
4	(a)	How a plant layout will be designed for sterile area?	5M
	(b)	Explain the personnel responsibilities in the organization.	5M

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

5	Write a note on ISO 9000.	5M
6	Discuss the process of equipment selection and purchase.	5M
7	Describe the organization and functioning of GLP facility.	5M
8	Differentiate batch and master formula record.	5M
9	Explain qualification of UV- Visible spectrophotometer.	5M
10	Write a note on rubber closures.	5M
11	Explain the handling of return goods and waste disposal.	5M
12	What are the tools and elements of QbD program?	5M
13	Explain briefly about factors to be considered in material management.	5M

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