THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 0321] MARCH 2021 Sub. Code: 2067

(SEPTEMBER 2020 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION

PCI Regulation SEMESTER – VI

PAPER VI – QUALITY ASSURANCE

Q.P. Code : 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Discuss the concept Quality by design. What are various elements and tools required for the same?
2. Discuss the concept, general provisions and protocols of GLP with reference to a nonclinical laboratory study.
3. What is good warehousing practices? Describe briefly material management in a warehouse.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Elements and philosophies of total quality management.
2. General principles of analytical method validation.
3. Brief overview of QSEM.
4. Purchase specifications and maintenance of stores for raw materials.
5. Quality control test for rubber closures.
6. Plant layout of pharmaceutical industry.
7. Quality review and quality documentation.
8. Batch formula records.
9. Benefits and elements of ISO 9000 and ISO 14000.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Principles of NABL Accreditation.
2. Master formula records.
3. Purpose of ICH guidelines.
4. Concept of GMP.
5. Quality audit.
6. Handling of return good.
7. Records and reports.
8. SOP.
9. Purchase specifications.
10. Validation master plan.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 0921] **SEPTEMBER 2021** **Sub. Code: 2067**

(SEPTEMBER 2020 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION
PCI Regulation 2017 - SEMESTER - VI
PAPER VI – QUALITY ASSURANCE
Q.P. Code : 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 x 10 = 20)**

1. What is the concept of TQM, describe in details various elements required for management of quality in pharmaceutical industry.
2. Explain the quality control tests for containers, rubber closures and secondary packing materials.
3. Compare calibration, qualification and validation. How do you prepare validation master plan? Describe calibration of UV-visible spectrophotometer.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. ICH stability testing guidelines.
2. Describe the principle of NABL accreditations.
3. Write details on GMP with respect to sanitation and hygiene.
4. Signification of equipment validation.
5. GLP for test and control articles.
6. Disqualification of testing facilities.
7. Complaints and evaluation of complaints.
8. Master formula record.
9. General principles of analytical method validation.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. SOP.
2. Batch formula records.
3. Waste disposal.
4. Concept of quality control.
5. Non clinical laboratory.
6. Tools and elements of Qbd.
7. Good warehousing practice.
8. Benefits of ISO 14000.
9. Quality managements.
10. General provision of GLP.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 0122] JANUARY 2022 Sub. Code: 2067
(MARCH 2021 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER VI – QUALITY ASSURANCE
Q.P. Code : 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Describe the design, construction and plant layout of Pharmaceutical Industry.
2. How complaints should be handled according to the GMP provisions? Elaborate recalling and handling of return goods.
3. What are the general principles of analytical method development? Compare accuracy and precision of LOD and LOQ with reference to ICH guidelines.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. QSEM with special emphasis on Q-series guidelines.
2. Compare calibration, qualification and validation.
3. Testing facilities operation and disqualifying of testing facilities.
4. Explain quality Audit.
5. Compare the concept of QA and QC as per GMP.
6. What are the general provisions of good laboratory practices?
7. How do you conduct a nonclinical laboratory study?
8. Quality control test for secondary packing materials.
9. Good warehousing practices.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Concept of quality assurance.
2. Elements of TQM.
3. Personal records.
4. Control of contamination.
5. Quality review.
6. Overview of Qbd.
7. Evaluation of complaints.
8. Distribution records.
9. Materials management.
10. Calibration of pH meter.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 0522] MAY 2022 Sub. Code: 2067

(SEPTEMBER 2021 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION

PCI Regulation SEMESTER - VI

PAPER VI – QUALITY ASSURANCE

Q.P. Code : 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. (a)Describe the process of harmonization of ICH guidelines.
   (b) Explain the ICH stability testing guidelines.
2. Discuss the responsibilities, training and hygiene of personnel.
3. (a) Explain the importance and types of validation.
   (b) Give the general principles of analytical method validation

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Explain the elements of quality by design program.
2. Discuss about equipment selection and purchase specifications.
3. Give a brief account of product recall.
4. Write a note on validation master plan.
5. Explain the good warehousing practices.
6. Write a note on batch formula record.
7. Discuss the protocol for conduct of a nonclinical laboratory study.
8. Explain the principles and procedures involved in NABL accreditation.
9. Discuss the quality control tests for glass container

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Quality assurance
2. Roles of head of production department
3. Standard operating procedure
4. Materials management
5. Control of contamination
6. Secondary packing materials
7. ISO 9000
8. Quality audit
9. Waste disposal
10. Control articles

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 1022] **OCTOBER 2022** **Sub. Code: 2067**
(MARCH 2022 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER VI – QUALITY ASSURANCE
Q.P. Code : 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 x 10 = 20)**

1. Explain about good laboratory practices.
2. Discuss the principles and procedures involved in NABL accreditation.
3. Explain the design, construction, plant layout and sanitation of premises.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. What are the steps for the registration of ISO 9000?
2. Write the qualification of UV-Visible spectrophotometer.
3. Discuss the quality control tests for rubber closures.
4. Describe Batch Formula Record.
5. Give a brief account on the maintenance of sterile areas.
6. Write a note on ICH stability testing guidelines.
7. Discuss the maintenance of stores for raw materials.
8. Write in detail about evaluation of complaints.
9. Write a note on good warehousing practice.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Quality control.
2. Calibration.
3. Control of contamination.
4. Handling of returned goods.
5. Types of validation.
6. Standard operating procedure.
7. Reports and documents.
8. Total quality management.
9. Secondary packing materials.
10. Quality by design tools.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0823] AUGUST 2023 Sub. Code: 2067
(MARCH 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER VI – QUALITY ASSURANCE

Q.P. Code: 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Describe the design, plant layout, maintenance and sanitation of premises.
2. Explain good laboratory practices.
3. Discuss about quality by design.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Discuss the calibration of pH meter.
2. Write the quality control tests for plastic containers.
3. Discuss about good warehousing practices.
4. Write a note on ICH stability testing guidelines.
5. Explain about quality documentation.
6. Write a note on personnel responsibilities.
7. Discuss about total quality management.
8. Explain about recalling and waste disposal.
9. Discuss about maintenance of equipment.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Quality control.
2. Hydrolytic resistance test for glass containers.
3. Distribution record.
4. User requirement specification.
5. Factory acceptance test.
6. Process validation.
7. Quality audit.
8. Q-series guidelines.
9. Control of contamination.
10. ISO 14000.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 1223] DECEMBER 2023 Sub. Code: 2067
(SEPTEMBER 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER VI – QUALITY ASSURANCE

Q.P. Code: 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Write a note on concepts and philosophy of GMP.
2. How are sanitation and sterile area are maintained in pharmaceuticals premises?
3. What is Quality Audit? What is the scope of Quality Audit?

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Write at least ten elements or criteria are followed in the ISO 9000 series standards.
2. What criterions are applied for the selection, purchase and maintenance of equipment?
3. Write notes on types of glasses used for manufacturing pharmaceutical containers.
4. What is the need of distribution records in industry?
5. Explain the importance of SOP.
6. Write a note on NABL accreditation.
7. Validation Master plan.
8. General principles of analytical method validity.
9. Qualification of UV – Visible spectrophotometer.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. ICH.
2. cGMP.
3. SOP.
4. Precision.
5. LOD.
6. LOQ.
7. Raw materials.
8. Secondary packing materials.
9. Training.
10. Quality documentation.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0524] **MAY 2024** **Sub. Code: 2067**

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER VI – QUALITY ASSURANCE

Q.P. Code: 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 x 10 = 20)**

1. Give a detail account on stability testing of dosage form as per ICH guidelines.
2. Define Good Laboratory Practices (GLP). Discuss the GLP provisions regarding the organization and personnel, Facilities, Equipment and Testing Facilities operation.
3. What is good warehousing practices? Discuss in detail about material management in a warehouse.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Write an account on TQM.
2. Describe the procedure for NABL accreditation.
3. Write a note on maintenance of stores for raw materials.
4. Describe the design, construction and plant layout in pharmaceutical industry.
5. Explain the quality control tests for secondary packing.
6. Classify the complaints and write about the evaluation of complaints.
7. Explain the contents of master formula record.
8. Discuss the parameters for qualification of UV-Visible spectrophotometer.
9. Explain about calibration, qualification and validation.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Define GMP.
2. Write the concept of QSEM.
3. Define QbD.
4. What is Purchase specification?
5. Disqualification of testing facilities.
6. What is materials management?
7. What is quality audit?
8. Write about quality documentation.
9. List out the quality control test for containers.
10. Write a note on calibration of pH meter.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 1024] OCTOBER 2024 Sub. Code: 2067
(SEPTEMBER 2024 EXAM SESSION)

B. PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER VI – QUALITY ASSURANCE

Q.P. Code: 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Write the principles and procedures of NABL accreditation.
2. Explain the quality control tests for containers, rubber closures and secondary packing materials.
3. Write the principles and procedure of calibration of pH meter.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Write the various elements of ISO 9000.
2. Differentiate between quality control and quality assurance.
3. Discuss the SOP for purchase specification.
4. Explain about personnel responsibilities, training and hygiene.
5. Write notes on testing facilities operation and disqualification of testing facilities.
6. Write about recalling and waste disposal procedures.
7. Explain the contents of batch formula record.
8. Describe the principles of analytical method validation.
9. Write a note on handling of return good.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. What is the purpose of ICH guidelines?
2. Enlist the benefits of ISO 14000.
3. Define TQM.
4. What is Control of contamination?
5. What is Nonclinical laboratory study?
6. What is Distribution record?
7. What is quality review?
8. What is SOP?
9. What is warehousing?
10. Write the scope of validation.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0325] **MARCH 2025** **Sub. Code: 2067**

B. PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER VI – QUALITY ASSURANCE

Q.P. Code: 562067

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 x 10 = 20)**

1. Discuss in detail the concepts of quality control, quality assurance and GMP.
2. Write the importance of Good Laboratory Practices. Explain briefly the protocol for conduct of a non-clinical laboratory study.
3. Discuss the scope, importance and types of validation processes.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Explain the elements of QbD.
2. Write in detail about ICH stability testing guidelines.
3. Explain the control of contamination in pharmaceutical industries.
4. Write about equipment selection, purchase specification and maintenance.
5. Explain the quality control tests for containers.
6. Describe SOP, quality audit and quality review.
7. Write about quality documentation.
8. Discuss the batch formula record.
9. Write a note on validation master plan.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. What are the benefits of ISO 9000?
2. Write the elements of TQM.
3. Write a note on maintenance of sterile areas.
4. Write the elements of ISO 14000.
5. Name the quality control test for secondary packing materials.
6. What is Records and reports?
7. Write the short notes on master formula record.
8. Write the handling of return good.
9. List the standards used for the qualification of UV-Visible spectrophotometer.
10. Define the term calibration.

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