BP 606 T

Total No. of Questions : 14] [Total No.of Pages : 01

III/IV B. PHARMACY (Supple) EXAMINATIONS, NOV/DEC- 2022

Sixth Semester

PHARMACEUTICAL QUALITY ASSURANCE - THEORY

Time : **Three Hours** Maximum : 75 Marks

SECTION - A

Answer any FIVE Questions. **5x10 = 50 M**

1. Define Quality by Design (QbD) and discuss the elements and tools of QbD program.
2. Write a note on Equipment selection and purchase specifications for equipments in pharmaceutical industry.
3. Discuss the Good laboratory practices for organization and personnel and testing facilities in Pharmaceutical Laboratories.
4. Enumerate the maintenance of Batch formula record and Master formula record along with their importance in pharmaceutical industry.
5. Define Validation. Write different types of validation and explain Validation Master Plan.
6. Sketch out a block diagram to explain plant layout for solid oral formulation unit. Add a note on environmental control maintainance in pharmaceutical industries.
7. Write a note on ICH stability testing guidelines.

SECTION - B

Answer any FIVE Questions. **5x5 = 25 M**

8. Write a short note on procedure of NABL Accreditation.
9. Define Total Quality Management (TQM) and discuss its elements.
10. Describe the maintainance of sanitization in Pharmaceutical Industry.
11. Write a note on personal responsibilities and hygiene in Pharmaceutical Industry.
12. Discuss the quality control tests for Packaging materials.
13. Write a brief outline on Good warehousing practice and management.
14. Write a brief note on quality audit and quality documentation maintainance in pharmaceutical industry.

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III/IV B. PHARMACY DEGREE EXAMINATIONS, JUNE / JULY -2022

Sixth Semester

PHARMACEUTICAL QUALITY ASSURANCE - THEORY

Time : **Three Hours**

Maximum : **75** Marks

SECTION - A

Answer any FIVE Questions. **5x10 = 50 M**

1. Discuss the purpose of ICH guidelines and add a brief outline on Q-series guidelines.
2. Write a detailed note on construction and plant layout aspects in pharmaceutical industry as per cGMP.
3. Discuss the quality control tests for different types of containers.
4. Write a note on quality audit and quality documentation in pharmaceutical industry.
5. Discuss the general principles of analytical method validation.
6. Define complaints and discuss the steps in handling of complaints.
7. Briefly outline the steps for registration to ISO 9000 and ISO 14000 and add a note on their benefits.

SECTION - B

Answer any FIVE Questions. **5x5 = 25 M**

8. Write the elements and tools of QbD program.
9. Briefly explain maintainance of stores for raw materials as per GMP guidelines.
10. Write a short note on general provisions as per Good Laboratory Practices (GLP).
11. Write a brief outline on importance of SOP and distribution records.
12. Briefly explain the calibration procedure for pH meter.
13. Discuss the objectives of materials management in warehousing.
14. Define the following :
    a) Quality assurance.
    b) Total Quality Management.
    c) Quality Control.
    d) Calibration.

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III/IV B. PHARMACY (SUPPLY) DEGREE EXAMINATIONS, FEBRUARY- 2022

Sixth Semester

QUALITY ASSURANCE - THEORY

Time : **Three Hours**

Maximum : **75** Marks

SECTION - A

Answer any FIVE Questions. **5x10 = 50 M**

1. Write in detail about total quality management and its different approaches.
2. Explain the environmental control parameters and maintenance of sterile area in production of parenteral preparations.
3. Discuss the quality control tests for glass and plastic containers in detail. Add a note on secondary packaging materials.
4. Describe the criteria to be taken for purchase and maintenance of equipment in a pharmaceutical industry.
5. Elaborate the differences between batch formula and master formula record.
6. Discuss validation master plan with schematic diagram. Write the importance of instrument qualification and calibration.
7. Write the procedure involved in qualification of UV-Visible spectrophotometer. Add a note on materials management in warehousing.

SECTION - B

Answer any FIVE Questions. **5x5 = 25 M**

8. What are the elemental tools of quality by design ?
9. Write the notes on ISO 9000 and its principles.
10. Describe product recalls and complaints.
11. Brief about design qualification and operational qualification.
12. Write the various types of validation and their significance.
13. Explain the protocol to conduct a non-clinical laboratory study.
14. Write in brief about the training and hygiene in a pharmaceutical industry.

Total No. of Questions :14]

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III/IV B.PHARMACY (Regular) DEGREE EXAMINATIONS, OCTOBER-2020

Sixth Semester

B.Pharmacy

QUALITY ASSURANCE-Theory

Time: Three Hours

Maximum marks: 75

SECTION-A

Answer any FIVE Questions. **5X10=50M**

1. What is the purpose of ICH guidelines and add a detail note on Q.B stability testing guidelines.
2. Explain detail about validation master plan and add a note on calibration of pH meter.
3. Discuss about the types of plant layout with advantages and limitations of each type and write the factors affecting desciging of plant layout.
4. a) Write the general principles of GLP and explain the protocol for conduct of non-clinical studies.
   b) Write about reporting and storage of non-clinical data.
5. Write a short note on
   a) SOP of any one analytical instrument in detail.
   b) Training and personal records.
6. Give an account on equipment selection, purchase specifications for equipment and raw materials.
7. Write in detail about GMP with respect to manufacturing of sterile dosage forms.

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SECTION-B

Answer any FIVE Questions. **5X5=25M**

8. Write a brief note on different stages in the process of NABL accreditation.
9. Explain the difference between Quality assurance and Quality control. Write the inter-relation of QA, QC and GMP.
10. Elaborate the responsibilities of personnel working in pharma manufacturing unit.
11. Write in brief about pharmacopoeial test for glass containers for sterile dosage forms.
12. Define and write differences and significance of qualification, validation and calibration.
13. Write about the basic functions of ware house and impact of bad ware housing practices.
14. Give a brief account on maintenance of sterile areas and control of contamination in manufacturing unit.