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Roll Number ---------- **(Total Number of Questions 13)** **(Total number of Printed Pages 01)**

Programme	B. Pharmacy
Semester	6th
Subject	Quality Assurance
Subject Code	BP606T
Paper ID	77991
Time	3Hours
Maximum Marks	75

Instructions to Candidates: *No supplementary/continuation sheet will be issued to the candidates. Answer the questions precisely.*
Section A consists of Ten parts of 2 marks each (Objective Type); Attempt **ALL.*
***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*
**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section A (10 X2 = 20)

1. Give very short answers to the followings (2 marks each):

i.	What are the purposes of QMS?
ii.	What is QbD?
iii.	What is a SOP and write its any two benefits?
iv.	What is electrostatic discharge (ESD)?
v.	What is VED Analysis?
vi.	Define Master Formula Record.
vii.	What is TQM?
viii.	What is Quarantine?
ix.	What are the different types of plastics?
x.	Define GLP.

Section B (2 X 10 = 20)

2.	Describe the National Accreditation Board for testing and calibration laboratories.
3.	Discuss in details about quality control tests of primary components.
4.	Discuss the design and construction requirements for pharma manufacturing according to GMP.

Section C (7 X 5 = 35)

5.	What is the protocol for conduct of a Non clinical laboratory study?
6.	What is validation? Discuss the various types of validation.
7.	Discuss the philosophies of TQM.
8.	What is QbD? Discuss its different elements in detail.
9.	Explain different types of recalls.
10.	Write a short note on raw material maintenance.
11.	Explain concept of ISO.
12.	Describe different methods of inventory control.
13.	Explain the disqualification of a facility.

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2/7/22 AM

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Section A (10 X2 = 20)

1. Give very short answers to the followings (2 marks each):

i.	Write in brief about Non-Clinical laboratory study.
ii.	Define QbD.
iii.	What do you mean by material management?
iv.	Define quality audit.
v.	What do you mean by performance qualification?
vi.	What is the purpose of ICH?
vii.	Define calibration.
viii.	What are benefits of ISO 14000?
ix.	Enlist the various tests performed for glass container.
x.	What is the difference between primary and secondary packaging?

Section B (2 X 10 = 20)

2.	What do you mean by validation? Write a detailed note on analytical method validation
3.	Explain in detail about environmental control in sterile areas.
4.	Give a detailed account on stability testing of dosage form as per ICH guidelines.

Section C (7 X 5 = 35)

5.	Define Total Quality management. What are the key elements of Total Quality management?
6.	Give an account of handling consumer complaints for pharmaceuticals.
7.	Write a note on Quality by Design tools.
8.	Discuss bracketing and matrixing design for stability testing.
9.	Define ISO. What are the steps involved in ISO 9000 registration process?
10.	Give an account on concurrent validation process.
11.	What is difference between calibration and validation?
12.	Discuss the role of QA in pharmaceutical industry.
13.	Write a short note on accuracy and precision determination during analysis.

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03 JUN 2023

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Section- A **(10X2=20)**

1.	Give very short answers to the followings
i.	What is ISO 14000?
ii.	What do you mean by Total Quality Management (TQM)?
iii.	What is the difference between calibration and validation?
iv.	What should be the frequency of HEPA filter integrity testing?
v.	Write the name of famous quality philosopher (guru)?
vi.	What is temper resistant packaging?
vii.	Define master formula record.
viii	What is material management?
ix.	What is the process analytical technology?
x.	Difference between primary and secondary packaging material.

Section- B **(2X10=20)**

2.	Describe the National Accreditation Board for Testing and Calibration Laboratories (NABL).
3.	Write about organization and personnel requirements in GLP.
4.	Discuss calibration of UV Visible spectrophotometer.

Section- C **(7X5=35)**

5.	What is QbD. Discuss its different elements in details?
6.	What is closure? Enlist different types of closures. Discuss their quality control tests.
7.	What is the procedure of purchase of equipment?
8.	Give a brief overview of QSEM with special emphasis on Q-series guidelines.
9.	Explain the complaint handling system.
10.	What is significance of SOP? Discuss the significance of reports and documents.
11.	What role does the head of production department and quality control department play in fulfilling the objectives of GMP?
12.	What is the protocol for conduct of a nonclinical laboratory student?
13.	Discuss in detail the contamination sources in pharma industry.

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241123
(Evening)

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****Section C consists of nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A (10X2=20)

1.	Give very short answers to the following:
i.	Describe any two responsibilities of the study director.
ii.	Write the name of a famous quality philosopher (guru).
iii.	What is validation? Discuss the various types of validation.
iv.	Classify the different types of plastics?
v.	Write the difference between primary and secondary packaging.
vi.	Write down the factors affecting the selection of process equipment in quality assurance.
vii.	What do you mean by quality audit?
viii.	What is process Analytical technology (PAT)?
ix.	Define SOP with its two benefits.
x.	What do you mean by good warehousing practices?

Section- B (2X10=20)

2.	What is QbD? Discuss its different elements in detail.
3.	Write about organization and personnel requirements in GLP.
4.	Discuss in detail the calibration of the UV Spectrophotometer.

Section- C (7X5=35)

5.	Briefly review quality control tests for primary components.
6.	Discuss the design and construction requirements for pharma manufacturing according to GMP regulations.
7.	Give a detailed account of the stability testing of dosage forms as per ICH guidelines.
8.	Write a short note on the complaint handling system.
9.	What is the protocol for conducting a Non- clinical laboratory study?
10.	Write a detailed note on the Batch Manufacturing Record.
11.	Write a note on National Accreditation Board for testing and calibration laboratories (NABL).
12.	Describe different methods to determine inventory control.
13.	Discuss the philosophies of TQM.

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120624 (Morning)

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***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*

****Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A **(10 X2 = 20)**

1.	Give a very short answers to the followings:
i.	What is meant by in-process control?
ii.	Define retrospective validation.
iii.	What does ICH Q10 refer to?
iv.	Define inventory control.
v.	What are the differences between quality control and quality assurance?
vi.	Define Standard Operating Procedures (SOPs).
vii.	Explain the concept of secondary packaging.
viii.	What is the full form of cGMP?
ix.	What is the purpose of vendor qualification?
x.	What is the objective of National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation?

Section- B **(2 X 10 = 20)**

2.	Explain in detail about the different types of validation protocols giving suitable example of pharmaceutical processes where they are applied.
3.	Define quality by design (QbD). Explain various techniques used in QbD along with their limitations.
4.	Write in detail structure, contents, and maintenance of master formula records.

Section- C **(7 X 5 = 35)**

5.	Distinguish between ISO 9000 and 14000.
6.	Write a short note on product recall procedure.
7.	What is GLP? What is its importance in the pharmaceutical industry?
8.	Give an account of quantitative scalability evaluation method (QSEM) guidelines.
9.	Discuss the types of consumer complaints and the process of handling them.
10.	Give an overview of the methods used for documentation in the pharmaceutical industry.
11.	What is the protocol for the conduct of a non-clinical laboratory study?
12.	Give a brief account of accuracy and precision determination during analysis.
13.	Discuss the quality control procedure for rubber closures.

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29 11 24 (E)

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Maximum Marks	75

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Section A consists of Ten parts of 2 marks each (Very Short Answer); Attempt **ALL.*
***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*
**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A **(10 X2 = 20)**

1.	Give very short answers to the followings:
i.	What are the purposes of QMS?
ii.	Define QbD.
iii.	What is a SOP and write it's any two benefits?
iv.	Write the scope of validation.
v.	Define VED analysis.
vi.	Define master formula record.
vii.	What is the TQM?
viii.	What is quarantine?
ix.	What are the different types of plastics?
x.	Define GLP.

Section- B **(2 X 10 = 20)**

2.	Describe the national accreditation board for testing and calibration laboratories.
3.	Write in details about quality control tests of primary components.
4.	Discuss about the design and construction requirements for pharma manufacturing according to GMP.

Section- C **(7 X 5 = 35)**

5.	What is the protocol for conduct of a non clinical laboratory study?
6.	What is validation? Discuss the various types of validation.
7.	Discuss the philosophies of TQM.
8.	What is QbD? Discuss its different elements in detail.
9.	Explain different types of recalls.
10.	Write a short note on raw material maintenance.
11.	What is the basis for quantitative analysis by UV-Vis?
12.	Describe different methods of inventory control.
13.	Explain the disqualification of a facility.

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240625

(evening)

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Section- B consists of **three questions**, each carrying **10 marks** (Long Answer Type); **Attempt any two.

****Section- C **consists of** nine questions, **each carrying** 5 marks **(Short Answer Type);** Attempt any seven.*

Section- A (10X2=20)

1.	Give very short answers to the followings:
i.	What is validation? List the various types of validation.
ii.	What are the different types of plastics?
iii.	State the basic needs of material management.
iv.	Mention any two responsibilities of a study director.
v.	What is the difference between primary and secondary packaging?
vi.	Define Batch Formula Record.
vii.	What is HVAC (Heating, Ventilation, and Air Conditioning)?
viii.	Name a famous quality philosopher (guru).
ix.	What is the difference between calibration and validation?
x.	What is Process Analytical Technology (PAT)?

Section- B (2X10=20)

2.	Discuss in detail the sources of contamination in the pharmaceutical industry.
3.	Discuss in detail the quality control tests for primary and secondary packaging components.
4.	Enlist the types of documents maintained in a pharmaceutical company. Write briefly about the Batch Formula Record.

Section- C (7X5=35)

5.	Write a note on pharmaceutical waste treatment and disposal.
6.	Write a note on the National Accreditation Board for Testing and Calibration Laboratories (NABL).
7.	Highlight the significance of personnel responsibilities.
8.	Write the calibration procedure for a UV spectrophotometer.
9.	Define ISO and outline the steps involved in the ISO 9000 registration process.
10.	Enumerate the different types of market complaints in the pharmaceutical industry.
11.	Give the design and construction requirements for pharmaceutical manufacturing as per GMP regulations.
12.	State the protocol for conducting a non-clinical laboratory study.
13.	Define QbD and illustrate its key elements in detail.

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09 12 25
(Morning)

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****Section -C consists of Nine questions carrying 5 marks each (Short Answer); attempt any SEVEN.*

Section- A **(10X2=20)**

1.	Give very short answers to the followings:
i.	What is meant by quality audit?
ii.	Define material management.
iii.	What is a batch formula Record?
iv.	Differentiate between primary and secondary packaging materials.
v.	What is ISO 14000?
vi.	How is contamination controlled in sterile areas?
vii.	What is QbD?
viii.	Define control articles.
ix.	What is NABL Accreditation?
x.	What is pareto analysis?

Section- B **(2X10=20)**

2.	Define Good Laboratory Practices (GLP). What are the objectives of GLP? Discuss the GLP provisions regarding the organization and personnel, facilities, equipment and testing facilities.
3.	Discuss the role of quality assurance department in equipment selection, framing purchase specifications, maintenance of stores and raw materials.
4.	Discuss the general principle of calibration. Also brief about analytical method validation.

Section- C **(7X5=35)**

5.	Enumerate different QM tools and explain fish bone diagram.
6.	Explain mixture design.
7.	What is the protocol for conduct of a non clinical laboratory study?
8.	What is product recall? Explain procedure of product recall.
9.	Write about the calibration of UV-visible spectrophotometer.
10.	Discuss the significance of personnel responsibilities.
11.	Enlist various quality control tests on containers. Explain hydrolytic resistance test on glass.
12.	What is GMP and cGMP? Discuss the benefits of GMP in pharmaceuticals.
13.	What is significance of SOP? Discuss the significance of reports and documents.

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