2/7/22 AM

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.	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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Note: Disclosure of identity by writing mobile number or making request for passing on any page of answer-sheet will lead to UMC against the candidate.

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**** 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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Roll No. | | | | | | | | | | |

Total No. of Pages : 02

Total No. of Questions : 22

B.Pharm (2017 Batch) (Sem.-6)

QUALITY ASSURANCE-THEORY

Subject Code : BP-606T

M.Code : 77991

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.**
2. **SECTION-B contains THREE questions carrying TEN marks each and students have to attempt any TWO questions.**
3. **SECTION-C contains NINE questions carrying FIVE marks each and students have to attempt any SEVEN questions.**

SECTION-A

Define briefly :

1. Difference between QA and QC
2. Master Formula Record
3. Quality audit
4. Validation
5. SOP
6. Material Management
7. Control Articles
8. Difference between primary and secondary packaging material
9. Line clearance
10. Pareto analysis

SECTION-B

11. ICH guidelines are divided into which major categories, enumerate them with codes and explain guidelines for stability testing.
12. Define QBD. What are different components of QBD? Discuss in brief.
13. Discuss the general principle of calibration. Also brief about Analytical method Validation.

SECTION-C

14. Define TQM. Enumerate components of TQM. Explain in detail any one of them.
15. Enumerate different quality management tools and explain fish bone diagram.
16. Explain Matrix design.
17. Briefly discuss ISO 14000
18. What are the principals of NABL Accreditation?
19. Discuss the significance of personnel responsibilities.
20. What is the procedure of purchase of equipments?
21. What is the protocol for conduct of A Non clinical Laboratory Study?
22. What is significance of SOP? Discuss the significance of reports and documents.

NOTE : Disclosure of identity by writing mobile number or making passing request on any page of Answer sheet will lead to UMC against the Student.