PAPER ID-420492

Roll No: | | | | | | | | | | | | | |

BPHARMA
(SEM VI) THEORY EXAMINATION 2021-22
QUALITY ASSURANCE– THEORY

Time: 3 Hours *Total Marks: 75*

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Define the term Calibration.
b.	Compare the qualification and validation of instruments.
c.	What is the definition of Quality by design (QbD).
d.	Define the Quality Control.
e.	Outline the role of quality documentation in pharmaceutical industries.
f.	Define the applications of Q-series guidelines in quality control and assurance.
g.	List the requirements for good laboratory practices.
h.	Summarize the role of environmental control for quality control.
i.	Define Batch formula record.
j.	Define the term GMP.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Write the principles and procedures of NABL Accreditation.
b.	Write a note on Total Quality management.
c.	Discuss the types of validation processes with their importance and the scope.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Explain the ISO 9000 guidelines.
b.	Discuss the procedure for maintenance of sterile areas and control of contamination in pharmaceutical industries.
c.	Write a note on Master formula record and SOP.
d.	Define complaints. Discuss the procedure for evaluation of complaints.
e.	Discuss the General Provisions of Good Laboratory Practices.
f.	Construct a short note on good warehousing practices.
g.	Outline the concept of total quality management with its elements and philosophies.

Printed Pages:01 *Sub Code: BP-606*

Paper Id: 236429 *Roll No.*

B.PHARM
(SEM VI) THEORYEXAMINATION 2022-23
QUALITY ASSURANCE

Time: 3 Hours ***Total Marks: 75***

Note: Attemptall Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt all questions in brief. ***10 x 2 = 20***

a Name the participants of ICH.

b) Differentiate QA and QC.

c Name the Ancillary areas.

(d) What is HVAC?

(e) What is Cobb's test?

(f) What refer to the subpart K in GLP? Define

(g) Packaging

(h) Outline the role of recalling.

(i) Give importance and scope of validation.

j Discuss general principles of qualification.

SECTION B

2. Attempt any two parts of the following: ***2 x 10 = 20***

(a) Explain ISO14000: overview, benefits, elements and steps of registration

(b) Discuss Design, construction and plant layout along with maintenance of organization premises in detail.

(c) Define calibration. Elaborate general principles of calibration, qualification and validation, types of validation along with validation master plan.

SECTION C

3. Attempt any five parts of the following: ***7 x 5 = 35***

(a) Describe in detail ICH Guidelines: purpose, process of harmonization, overview of QSEM and Q-series Guidelines.

b) Write short note Definition, elements, philosophies of Total Quality Management (TQM).

(c) Write short note on:

(i) Quality control tests for Plastic Containers

(ii) Quality control tests for Metal Containers

(d) Discuss purchase specifications and maintenance of stores for raw materials.

(e) Discuss about Protocol for conduct of Non-Clinical Laboratory study.

(f) Explain in detail about Master Formula Record and SOP.

(g) Elaborate method of Qualification of UV-Visible spectrophotometer andGeneral principles of Analytical method Validation

PAPER ID-410550

Subject Code: BP606T

Roll No: | | | | | | | | | | | | | |

BPHARM
(SEM VI) THEORY EXAMINATION 2023-24
QUALITY ASSURANCE THEORY

TIME: 3 HRS **M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	What is thepurpose of warehousing?
b.	Why formulations in pharmaceutical industry are prepared batch wise?
c.	Mention benefits of getting ISO Certification.
d.	What do you understand by calibration curve? Why do we need it?
e.	Mention the names of QC Tests of Glass.
f.	What is Total quality management (TQM)?
g.	Write Steps involved in complaint handling.
h.	Mention regulatory body of Australia.
i.	Quality by design (QbD) is an initiative of?
j.	Define retrospective validation.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Whatdo youunderstandbythe term "Validation"? Explain its types and purpose of validation.
b.	Discuss in detail about quality control test for containers.
c.	Discuss in detail about good warehousing practice

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	
b.	Discuss Protocolfor Conduct ofa NonclinicalLaboratory Study.
c.	What is the purpose of ISO? Write in brief about ISO 9000 and ISO 14000
d.	Discuss about Qualification of UV-Visible spectrophotometer
e.	Write in detail about Batch Formula Record (BFR).
f.	Discuss in detail about complaints and evaluation of complaints.
	Write about personal responsibilities associated with Quality control (QC) department. Also discuss about control of contamination in pharmaceutical industry. Discuss quality by design in detail.
g.	

Paper Id 250787

Roll No:

BPHARM
(SEM VI) THEORY EXAMINATION 2024-25
QUALITY ASSURANCE– THEORY

TIME: 3 HRS **M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Define the term SOP.
b.	Differentiate between primary and secondary packaging materials.
c.	Write the significance of calibration.
d.	Write any three parameters each for GMP and TQM.
e.	Discuss importance of calibration curve.
f.	Define Batch Formula Record.
g.	Name the requirements for Good Laboratory Practices.
h.	What refer to the subpart K in GLP?
i.	Write about quality documentation.
j.	What do you mean by Quality by design (QbD)

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Describe the design, plant layout, maintenance and sanitation of premises.
b.	Give a detail account on stability testing of dosage form as per ICH guidelines.
c.	What do you understand by the term "Validation"? Explain its types and purpose of validation.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Discuss Protocol for Conduct of a Nonclinical Laboratory Study.
b.	Discuss in detail about complaints and evaluation of complaints.
c.	Explain the principles and procedures involved in NABL accreditation.
d.	Explain about recalling and waste disposal.
e.	Discuss calibration of UV-Visible spectrophotometer.
f.	Write in detail about Quality Review and Quality documentation.
g.	What is the purpose of ISO? Write in brief about ISO 9000 and ISO 14000.

Roll No:

BPHARM
(SEM. VI) THEORY EXAMINATION 2025-26
QUALITY ASSURANCE– THEORY

TIME: 3 HRS **M.MARKS: 75**

Note: Attempt all Sections. In case of any missing data; choose suitably.

SECTION - A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Define Quality Assurance and Quality Control.
b.	What is GMP?
c.	Define Total Quality Management (TQM).
d.	What is QbD (Quality by Design)?
e.	Define ICH guidelines.
f.	What is NABL accreditation?
g.	Define Good Laboratory Practices (GLP).
h.	What is Batch Manufacturing Record (BMR)?
i	Define calibration.
j.	What is validation?

SECTION - B

2. Attempt any twoof the following:2 x 10 = 20

a.	Explain ICH guidelines with special emphasis on Q-series and stability testing guidelines.
b.	Discuss organization and personnel requirements in pharmaceutical industry along with training and hygiene practices.
c.	Explain calibration and validation in detail, including types of validation and validation master plan.

SECTION - C

3. Attempt any fiveof the following: **7 x 5 = 35**

a.	Describe Quality Assurance and Quality Management concepts with differences between QA and QC.
b.	Explain ISO 9000 and ISO 14000 standards, their elements and benefits.
c	Discuss design and maintenance of pharmaceutical premises including environmental control and contamination prevention.
d	Explain quality control tests for containers, rubber closures and packaging materials.
e	Write a note on complaint handling, product recall and waste disposal.
f	Discuss documentation in pharmaceutical industry including BMR, MFR, SOP and distribution records. https://www.aktuonline.com
g	Explain analytical method validation and calibration of pH meter and UV-Visible spectrophotometer.