PAPER ID-310135

Subject Code: BP702T

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

B PHARM
(SEM VII) THEORY EXAMINATION 2020-21
INDUSTRIAL PHARMACY-II

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.	Enlist the GMP consideration required for pilot plant studies.
b.	What is the purpose conduction of pilot-plant scale up studies?
c.	Define technology transfer. Enlist the names of Indian agencies which are involved in technology transfer process.
d.	What is process validation?
e.	What is meant by regulatory affairs? Why regulatory affairs are essential for pharmaceutical industry?
f.	Expand the terms: INDA, NDA, ANDA, IB.
g.	Write the names of the laboratories which are governed by CDSCO.
h.	What is COPP? Why is it required?
i.	Explain the terms: TQM and QbD. Write the benefits of QbD.
j.	What is the role of six-sigma in pharmaceuticals.

SECTION B

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

a.	Who is the Drug Controller General of India? Describe the organization and functions of CDSCO. Write the functions of the laboratories governed by CDSCO.
b.	Explain in detail about NDA. How ANDA is different from NDA?
c.	What is the importance of technology transfer in pharmaceutical industry? Write a note on NRDC.

SECTION C

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

a.	Explain in detail about SUPAC guidelines.
b.	What is QRM? What are the principles involved in QRM? Explain the process of QRM.
c.	What are the functions of different TOT related documents in industrial pharmacy?
d.	Explain in detail about INDA.
e.	What is the methodology involved in six-sigma process? Explain the different levels.
f.	What is ISO 9000? How does ISO 9000 series of quality systems standards differ from ISO 14000?
g.	Write a brief note on NABL and OOS.

Subject Code: BP702T

PAPER ID-410405

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

B PHARM
(SEM VII) THEORY EXAMINATION 2021-22
INDUSTRIAL PHARMACY II

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.	Mention two major applications of platform technology.
b.	Mention the basic role of SUPAC guidelines.
c.	Name at least 4 agencies responsible for successful technology transfer in India.
d.	State the role of one major TT agency of India.
e.	State to important functions of the Regulatory Affairs Department.
f.	What do you mean by 'Non-Clinical Drug Development'?
g.	What do you mean by 'Six Sigma concept,'?
h.	Mention the specifications of ISO 14000 series of quality systems standards.
i.	State the responsibilities of CDSCO.
j.	Mention the significance of COPP.

SECTION B

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

a.	State and explain the Technology transfer protocol following WHO guidelines.
b.	Describe the steps of data presentation for FDA Submissions.
c.	Give a brief idea on regulatory requirements and approval procedures for new drugs.

SECTION C

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

a.	Explain the significance of personnel requirements in pilot plant scale up.
b.	Describe the steps for technology transfer from RD to production.
c.	State and explain the legal issues during technology development and transfer.
d.	Explain the responsibilities of the regulatory affairs professionals.
e.	Define clinical research and state the clinical research protocols.
f.	Write a brief note on the concept of Quality by Design (QbD).
g.	Describe the functionalities of the Central Drug Standard Control.

Printed Pages:01 **Sub Code: BP702T**

Paper Id: 2 3 1 3 3 0 **Roll No.** | | | | | | | | | | |

B PHARM
(SEM VII) THEORY EXAMINATION 2022-23
INDUSTRIAL PHARMACY II

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

Note: 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 Pilot Plant.
(b) Describe Platform Technology.
(c) Define Confidentiality Agreement.
(d) Discuss the practical aspects of Commercialization.
(e) Explain Drug metabolism and Toxicology.
(f) Quote the responsibilities of Regulatory affairs professionals.
(g) Define ISO 14000.
(h) Write a short note on GLP.
(i) Define CDSCO.
(j) Define Certificate of Pharmaceutical Product (COPP).

SECTION B

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

(a) What are SUPAC Guidelines. Explain the SUPAC guidelines for immediate release dosage forms.
(b) Outline Quality Risk Management. Discuss the various risk management tools and methodologies.
(c) Explain :
  (i) Total Quality Management
  (ii) Out of Specification
  (iii) Change Control
  (iv) ISO 9000 series

SECTION C

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

(a) Describe the pilot plant scale up considerations for solid dosage forms.
(b) Discuss the significance of space requirements and raw materials in pilot plant set up.
(c) Explain various Technology Transfer agencies in India.
(d) Outline Validation and Qualification. Write a short note on Analytical Method Transfer.
(e) Summarize Investigational Brochure. What do you understand by IND.
(f) Describe Six Sigma Concepts.
(g) Explain the organization structure and responsibilities of CDSCO.

PAPER ID-311133

Roll No:

BPHARM
(SEM VII) THEORY EXAMINATION 2023-24
INDUSTRIAL PHARMACY II – THEORY

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

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

SECTION A

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

a.	Define platform technology.
b.	Name the relevant documents for pilot plant scale-up considerations for solid dosage forms.
c.	Mention the role of the TT agencies in India.
d.	State the technology transfer protocol.
e.	State the role of the Regulatory Affairs department.
f.	State the general considerations of IND.
g.	Define OOS.
h.	State the QbD approach.
i.	State the responsibilities of CDSCO.
j.	Mention the regulatory requirements for new drugs.

SECTION B

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

a.	Elaborate the significance of the requirements of personnel, space and raw materials in Pilot plant scaling up.
b.	Describe the steps and protocol involved in quality risk management.
c.	Write how Biostatistics plays a major role in pharmaceutical product development.

SECTION C

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

a.	Explain the significance and applications of SUPAC guidelines.
b.	Explain the significance of the technology transfer protocol.
c.	Describe the various components of granularity of the TT process.
d.	Write down the construction and responsibilities of two major regularity authorities associated with technology transfer.
e.	Explain the important considerations of the non-clinical drug development.
f.	State and explain the specifications of ISO 9000 and ISO 14000 series of quality systems standards.
g.	Explain the roles and responsibilities of the State Licensing Authority.

Subject Code: BP702T

PAPER ID-410865

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

BPHARM
(SEM VII) THEORY EXAMINATION 2023-24
INDUSTRIAL PHARMACY II 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.	Write the benefits of technology transfer.
b.	Define NRDC.
c.	Write the responsibilities of regulatory affair department.
d.	Define six sigma concept.
e.	Define out of specifications (OOS).
f.	Write the purpose of establishing CDSCO.
g.	Write the requirement of regulatory affairs in technology transfer.
h.	Write the purpose of investigational brochure.
i.	Define QbD.
j.	Write the Functions of NABL.

SECTION B

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

a.	Discuss the pilot plant scale up considerations for solid dosage forms.
b.	Write the WHO guidelines for technology transfer.
c.	Describe the regulatory requirements and approval procedures for New Drugs.

SECTION C

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

a.	Discuss SUPAC guidelines.
b.	Describe quality risk management.
c.	Describe the regulatory requirements of Non-Clinical Drug Development.
d.	Describe the general considerations of investigational new drug.
e.	Write the role of Biostatistics in Pharmaceutical Product development.
f.	Describe the ISO 9000 series of quality systems standards.
g.	Discuss the regulations for Management of Clinical Studies.

Subject Code: BP702T

PAPER ID-310286

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

BPHARM
(SEM VII) THEORY EXAMINATION 2024-25
INDUSTRIAL PHARMACY II – 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.	Explain in brief about confidential agreement checklist.
b.	Enumerate the connection of regulatory affairs department with other department in company.
c.	What are the steps involving in Scale- up?
d.	Mention the various contents of technology transfer dossier.
e.	Mention the dimensions of Quality.
f.	Explain in brief about NABL and its scope.
g.	Short note on Six Sigma Concept and its levels.
h.	Enlist the reasons for occurrence of OOS (Out of specifications).
i.	Enlist the principles and key elements of TQM.
j.	Explain in brief about application of Biostatistics in pharmaceutical product development.

SECTION B

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

a.	Describe the organization and functions of Central drug regulatory Authority in India.
b.	What are Bioequivalence studies and Biowaivers? Describe in detail.
c.	Define pilot-plant and relation between pilot-plant and scale -up. Describe pilot-plant scale -up considerations for solids in detail.

SECTION C

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

a.	Explain QBD in detail. Discuss its importance in pharmaceuticals.
b.	Describe in detail about general considerations of Investigational New drug (IND) application
c.	What is quality risk management? Explain QRM process along with its tool.
d.	Explain the types and methods of technology transfer.
e.	Explain the modules of CTD in detail.
f.	Explain in detail the section that deals with changes in excipient in the drug product as per SUPAC guideline.
g.	What are the steps in obtaining ISO 9000 series certifications?

Paper ID : 250233

Printed Page: 1 of 1
Subject Code: BP702T

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

BPHARMA
(SEM VII) THEORY EXAMINATION 2024-25
INDUSTRIAL PHARMACY II – 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 technology transfer?
b.	Mention the role of TT agencies in India.
c.	What is state process validation?
d.	State two major objectives of pilot plant Scale-up.
e.	Write full form of SUPAC and its purpose
f.	Mention key roles of the regulatory affairs department.
g.	Define quality by design(QBD)
h.	Mention the two key responsibilities of CDSCO.
i.	What is the significance of COPP?
j.	What do you understand by non clinical drug development?

SECTION B

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

a.	Describe the regulatory requirements and approval process of new drug.
b.	Write the WHO guideline for technology transfer and also discuss about TT authorities in India.
c.	Define CDSCO. Organizational Framework and Operational Scope of CDSCO.

SECTION C

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

a.	Write the pilot plant scale up techniques for the solid dosage form.
b.	Explain in detail about SUPAC Guidelines.
c.	Discuss about Quality risk management. Explain QRM process with its principal.
d.	Describe the steps involve in data presentation for FDA submission.
e.	Write a short note on regulatory requirements and approval process for new drug approval.
f.	Explain the concept and benefits of Quality by Design(QBD) in detail.
g.	Define ISO. What are ISO 9000 and ISO 14000? How does the ISO 9000 series Quality system standard differ from ISO 14000?