



PAPER ID-310135

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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.



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

Time: 3Hours**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.	
b.	State and explain the Technologytransfer protocol following WHO guidelines.
c.	Describe the steps of data presentation for FDA Submissions.
	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.	
b.	Explain the significanceof personnelrequirements in pilot plant scale up.
c.	Describe the steps for technology transfer from RD to production.
d.	State and explain the legal issues during technology development and transfer.
e.	Explain the responsibilities of the regulatory affairs professionals.
f.	Define clinical research and state the clinical research protocols.
g.	Write a brief note on the concept of Quality by Design (QbD).
	Describe the functionalities of the Central Drug Standard Control.

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

Time: 3Hours**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.



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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 regulatory 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.



PAPER ID-310286

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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**

b.	Explain in brief about confidential agreement checklist.
c.	Enumerate the connection of regulatory affairs department with other department in company.
d.	What are the steps involving in Scale- up?
e.	Mention the various contents of technology transfer dossier.
f.	Mention the dimensions of Quality.
g.	Explain in brief about NABL and its scope.
h.	Short note on Six Sigma Concept and its levels.
i.	Enlist the reasons for occurrence of OOS (Out of specifications).
j.	Enlist the principles and key elements of TQM.
	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**

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



PAPER ID-311037

Roll No:

BPHARM
(SEM VII) THEORY EXAMINATION 2025-26
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.	Define SUPAC.
b.	Write the importance of analytical method transfer.
c.	Define "non clinical drug development".
d.	Define COPP.
e.	Write the components of ISO 14001.
f.	Define post market surveillance phase IV.
g.	Write a short note on USFDA.
h.	Write the significance of "measurement of central tendency"
i.	Define GLP.
j.	Define NRDC.

SECTION B

2. Attempt any two parts of the following:

2 x 10 = 20

a.	Discuss the term 'Pilot Plant Scale-Up' in the context of solid dosage form manufacturing.
b.	Write the role of regulatory affairs department in a pharmaceutical industry.
c.	How ISO 9000 series ensures quality system standards?

SECTION C

3. Attempt any five parts of the following:

7 x 5 = 35

a.	Discuss the WHO guidelines of technology transfer.
b.	What is a platform, write its types and explain platform technology.
c.	Write the specifications of premises and equipment's utilized in technology transfer protocol.
d.	Write a note on safety, efficacy and risk assessments of NDA.
e.	What do you mean by QbD; Discuss about critical quality attributes?
f.	State the primary distinction between CDSCO and the state licensing authority in drug and device regulations.
g.	Discuss the granularity of technology transfer process.