26/11/21 M

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

Programme	B. Pharmacy
Semester	7th
Subject	Industrial Pharmacy-II
Subject Code	BP702T
Paper ID	78388
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 recommended storage conditions for empty capsules shells in a pilot plant?
ii.	Enlist the different types of manufacturing changes with suitable examples.
iii.	Define Change Control.
iv.	Differentiate Qualification and Validation.
v.	Write down the full form and use of INDA and NDA.
vi.	Enlist the different teams with their prime work framed during drug development process.
vii.	What is the major difference between ISO9000 and ISO14000?
viii.	What is DMAIC in Six Sigma concept?
ix.	Write the full form of CDSCO.
x.	Why COPP is required by pharmaceutical industry?

Section B (2 X 10 = 20)

2.	What is the meaning and significance of pilot plant scale-up in Pharma industry? Strengthen your comments with suitable example.
3.	Discuss the organization and function of CDSCO with special mention to its port offices. What are the requirement and various steps of approval of any drug in India?
4.	Differentiate INDA with NDA. Describe the content and format of INDA with special mention to investigators brochure.

Section C (7 X 5 = 35)

5.	Discuss different types of Platform technology with their importance.
6.	Give a brief account on SUPAC guidelines.
7.	Discuss the role of Biostatistics in pharmaceutical development.
8.	Write in brief about the various TT agencies in India.
9.	Write the organization and functions of State Licensing Authority.
10.	What are the major components of TQM? Discuss the significance of TQM in pharmaceutical industry
11.	Describe the significance of technology transfer and quality risk management in Pharmaceutical industry.
12.	What are the different elements and goals of Pharmaceutical QBD?
13.	What are the requirements and various steps of approval of any drug in India? If, a drug is already approved in any other country, discuss the utility of COPP.

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2/7/22 M

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Semester	7th
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Subject Code	BP702T
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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 is Platform technology?
ii.	Define Granularity.
iii.	Enlist different phases of Clinical trials.
iv.	What is CDSCO?
v.	Define Quality Assurance.
vi.	What is SUPAC?
vii.	Define Quality by Design (QbD).
viii.	Define Technology Transfer.
ix.	What is COPP?
x.	Define Investigational New Drug (IND).

Section B (2 X 10 = 20)

2.	What do you mean by "Pilot scale up"? Discuss various pilot plant scale up consideration for solids.
3.	Discuss WHO Guideline on Transfer of Technology in Pharmaceutical Industry.
4.	Describe role and importance of Good Laboratory Practices (GLP) in pharmaceutical industry.

Section C (7 X 5 = 35)

5.	Describe the approach of QbD in quality management system.
6.	Write a short note on quality control and analytical method transfer.
7.	Discuss platform technology with its importance.
8.	Discuss approval procedure of new drug in India.
9.	Write a short note on Quality management system.
10.	Write various functions of CDSCO.
11.	Discuss the SUPAC with various change levels in brief.
12.	Write a short note on prerequisites to establish a technology platform for early development.
13.	Describe clinical research protocol.

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

1.	Give very short answers to the followings:
i.	What is pilot plant?
ii.	What is scale-up?
iii.	Define quality risk management.
iv.	Mention the names of TT agencies of India.
v.	Define regulatory affairs.
vi.	What are regulatory authorities?
vii.	Write the importance of quality by design.
viii.	What are six sigma concepts?
ix.	What is CDSCO?
x.	Define COPP.

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

2.	Explain in detail scale- up considerations for solid dosage forms.
3.	Describe the role, responsibility, objectives and functions of regulatory affairs in detail.
4.	Discuss in detail the regulatory requirements for approval for new drug.

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

5.	Explain about SUPAC guidelines.
6.	Discuss platform technology in detail.
7.	Write and elaborate technology transfer protocol.
8.	Explain about Technology Transfer (TT) related documentation.
9.	Discuss general considerations of INDA and NDA.
10.	What are clinical trials? Write about different types of clinical trials.
11.	What is quality? Explain the concept of total quality management (TQM) in detail.
12.	Write the organization and functions of state licensing authority.
13.	Write the organization and functions of CDSCO.

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12 JUN 2023

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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-
i.	What is pilot plant?
ii.	What is scale-up?
iii.	What is NRDC?
iv.	What is qualification and validation?
v.	Define regulatory affairs.
vi.	What is NDA?
vii.	Write the importance of quality by design.
viii.	What is change control?
ix.	Define COPP.
x.	What is CDSCO?

Section- B (2 X 10 = 20)

2.	Explain in detail pilot plant scale-up considerations for semi solids.
3.	Describe in detail the role, responsibility, objectives and functions of regulatory affairs department.
4.	Explain in detail the concept of quality and total quality management.

Section- C (7 X 5 = 35)

5.	Discuss platform technology in detail.
6.	Explain about SUPAC guidelines.
7.	Explain the TT agencies in India.
8.	Discuss the technology transfer protocol.
9.	Discuss general considerations of investigational new drug (IND) application and NDA.
10.	Explain about clinical research and BE studies.
11.	Write about the ISO 9000 series of quality systems standards.
12.	Write the organization and responsibilities of state licensing authority.
13.	Write the organization and responsibilities of CDSCO.

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30 1 1 23 (Seventh)

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

Programme	B. Pharmacy
Semester	7th
Subject	Industrial Pharmacy-II
Subject Code	BP702T
Paper ID	78388
Time	3Hours
Maximum Marks	75

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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 following:
i.	What are the benefits of NABL accreditation?
ii.	Define Bioavailability and Bioequivalence.
iii.	Define Change control.
iv.	What is the need for pilot plant studies in pharmaceutical industries?
v.	Enlist functions of regulatory authorities
vi.	Write a note on IQ, OQ and PQ.
vii.	What is Scale-up?
viii.	Write a statement Technology transfer means the physical transfer of goods'. True or False.
ix.	What are the regulatory requirements for approval of new drugs?
x.	Write the vision and mission of CDSCO.

Section B (2 X 10 = 20)

2.	Explain the features of finished product technology transfer as per WHO guidelines
3.	What are the SUPAC Guidelines? Enumerate the studies required to be performed for the production of Liquid oral dosage form.
4.	Discuss the regulatory requirements and approval procedures for New Drugs.

Section C (7 X 5 = 35)

5.	What are the requirements and various steps of approval of any drug in India? If, a drug is already approved in another country, discuss the utility of COPP.
6.	Write a note on the Investigator's Brochure.
7.	What are the major components of TQM? Discuss the significance of TQM in the pharmaceutical industry.
8.	Write about QbD and its application.
9.	What is a confidentiality/Non-disclosure Agreement? Outline the CDA agreement document.
10.	Describe different phases of clinical trials.
11.	Write about a note on the ISO 9000 series.
12.	Explain in detail about the scale- up techniques for solid dosage forms (Tablets/Capsules).
13.	Discuss transfer of technology between R&D and manufacturing unit.

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

Programme	B. Pharmacy
Semester	7th
Subject	Industrial Pharmacy-II
Subject Code	BP702T
Paper ID	78388
Time	3Hours
Maximum Marks	75

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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 are the benefits of ISO 14000 accreditation?
ii.	Define bioavailability and bioequivalence.
iii.	Define six sigma concepts.
iv.	What is the need of pilot plant studies in pharmaceutical industries?
v.	Give the role of regulatory affairs.
vi.	Write a note on IQ, OQ and PQ.
vii.	What is platform technology?
viii.	Define 'technology transfer'. Give the general principle in the technology transfer process.
ix.	What are the regulatory requirements for approval of new drugs?
x.	Write a note on CDSCO.

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

2.	Explain the features of finished product technology transfer as per WHO guidelines.
3.	What are the SUPAC Guidelines? Enumerate the studies required to be performed for production of solid oral dosage form.
4.	Differentiate in-between INDA and NDA. Describe the content and format of INDA with reference to investigators brochure.

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

5.	What are the requirements and steps for drug approval in India? Additionally, how does COPP aid in the approval process for drugs already approved in other countries.
6.	Write the organization and functions of state licensing authority.
7.	What are the major components of TQM? Discuss the significance of TQM in pharmaceutical industry.
8.	Discuss terms "QTPP" and "CQA" concerning QbD and its application.
9.	What is confidentiality non-disclosure agreement? Draw an outline of CDA agreement document.
10.	Explain the principles of good laboratory practice.
11.	Describe different models for the statistical design of clinical trials.
12.	Explain the procedure for pilot plant scale up for liquid dosage form.
13.	Write a note on master formula record.

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20/11/24 E

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

Programme	B. Pharmacy
Semester	7th
Subject	Industrial Pharmacy-II
Subject Code	BP702T
Paper ID	78388
Time	3Hours
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 (10X2=20)

1.	Give very short answers to the followings:
i.	What is scale-up?
ii.	What do you mean by 'six sigma concept,'?
iii.	Mention applications of platform technology.
iv.	What are the regulatory requirements for approval of new drugs?
v.	Write about GMP considerations in pilot plant scale up.
vi.	State vision and mission of CDSCO.
vii.	What are the components of 'non-clinical drug development'?
viii.	What are the three aspects of TQM?
ix.	Benefits of NABL accreditation.
x.	Differentiate between IQ, OQ and PQ.

Section- B (2X10=20)

2.	Describe the steps of data presentation for FDA Submissions.
3.	Describe about TT agencies in India.
4.	What are the SUPAC guidelines? Enumerate the studies required to be performed for production of liquid oral dosage form.

Section- C (7X5=35)

5.	Write a brief note on the concept of quality by design (QbD) and its application.
6.	Describe about the responsibilities of state licensing authority.
7.	Give an account of analytical method transfer.
8.	Describe the steps for technology transfer from RD to production.
9.	Summarize the biostatistics in pharmaceutical product development.
10.	What is confidentially/non-disclosure agreement? Draw an outline of CDA agreement document.
11.	What are the requirements and various steps of approval of any drug in India?
12.	Write a note on Investigator's brochure.
13.	Explain in detail about the scale up techniques for solid dosage form (Tablets).

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(Evening)

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

Programme	B. Pharmacy
Semester	7th
Subject	Industrial Pharmacy II
Subject Code	BP702T
Paper ID	78388
Time	3Hours
Maximum Marks	75

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Section- A consists of **ten questions, each carrying **2 marks** (Very Short Answer Type); **Attempt all.***
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.	Mention two major applications of platform technology.
ii.	Define pilot plant.
iii.	What do you mean by the 'Six Sigma' concept?
iv.	Define ISO 14000.
v.	Write a short note on GLP.
vi.	Explain drug metabolism and related technologies.
vii.	Mention the responsibilities of regulatory affairs professionals.
viii.	Mention key considerations in an IND application.
ix.	State the responsibilities of CDSCO.
x.	Mention the role of technology transfer (TT) agencies in India.

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

2.	What are SUPAC guidelines? Explain the SUPAC guidelines for immediate-release dosage forms.
3.	Describe how biostatistics plays a major role in pharmaceutical product development.
4.	Give a brief overview of regulatory requirements and approval procedures for new drugs.

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

5.	List out and explain the steps and protocols involved in Quality Risk Management.
6.	Highlight the roles and responsibilities of the State Licensing Authority.
7.	Enumerate the pilot plant scale-up considerations for solid dosage forms.
8.	Discuss briefly the terms validation and qualification. Add a note on analytical method validation.
9.	Mention the important considerations in non-clinical drug development.
10.	Summarize the concept of Quality Risk Management and name key risk management tools.
11.	Outline the steps involved in technology transfer from R&D to production units.
12.	Present a brief note on the concept and application of Quality by Design (QbD).
13.	Define clinical research and list the essential components of a clinical research protocol.

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26 DEC 2013

(Evening)

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

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

1.	Give very short answers to the followings:
i.	What are the objectives of Pilot plant scale-up?
ii.	Enlist the limitations of SUPAC.
iii.	What are the components of MoUs?
iv.	Name the regulatory agencies of India, USA, UK and Canada.
v.	What are the principles of TQM (Total quality management)?
vi.	Outline the objectives of Central Drug Standard Control Organization (CDSCO).
vii.	Enlist the technology transfer agencies in India.
viii.	Summarize the objectives of NABI.
ix.	Define quality by design (QbD).
x.	What is Six Sigma concept?

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

2.	Explain general considerations for Pilot plant scale-up techniques.
3.	Discuss WHO guidelines for technology transfer.
4.	Illustrate the functions of Central Drug Standard Control Organization (CDSCO).

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

5.	Discuss about ISO14000.
6.	Describe the functions of State licensing authority.
7.	Summarize the functions and objectives of Good Laboratory Practice (GLP).
8.	Write a note on pharmaceutical products.
9.	Discuss the role of biostatistics in pharmaceutical product development.
10.	Briefly discuss change control.
11.	Illustrate the different types of licensing agreements.
12.	Discuss in brief about New Drug Application (NDA).
13.	Write a note on the management of clinical studies.

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