Code No: D-8310/PCI

FACULTY OF PHARMACY
M. Pharmacy (Pharm. Quality Assurance) I- Semester (PCI) Main Examination, May 2022
Subject: Quality Management Systems

Time: 3 hours **Max Marks: 75**

Note: Answer any Five from the following questions. (5x15= 75 Marks)

1. a) Explain in detail the significance of Vision and mission statements in an industry. (8)
   b) Explain the concept of Pharmaceutical quality management based on ICH QI0. (7)

2. a) Explain management of risk as per ICH Q9 guidelines (8)
   b) With the help of a flow chart explain the benchmarking of a quality process.(7)

3. a) Write a note on cost optimizing strategies. (8)
   b) Write a note on NABL certification and accreditation. (7)

4. a) Explain the scope of ISO 9001: 2015. (8)
   b) What is annual product review? Why is it compiled? (7)

5. a) What are Out of specification and Out of trends? Explain. (8)
   b) What are control charts? Give their applications. (7)

6. Define Statistical Process Control (SPC). What is the importance of SPC in pharmaceutics? What are the advantageous of statistical control? (15)

7. What is cost of quality? Explain the various models of cost of quality. Write a note on six sigma. (I5)

8. a) Explain the stability testing conditions as per ICH guidelines. (8)
   b) Explain the role of HACCP in risk management. (7)

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Code No: D- 8311/PCI

FACULTY OF PHARMACY
M. Pharmacy (Pharm. Quality Assurance) I- Semester (PCI) Main Examination, May 2022

Subject: Quality Control and Quality Assurance

Time: 3 hours **Max Marks: 75**

Note: Answer any Five from the following questions. (5 x 15 = 75 Marks)

1. Describe the concept and evolution of Quality Control and Quality Assurance.

2. Discuss the Good Laboratory Practices for a quality control laboratory in detail.

3. Explain the various CPCSEA guidelines for laboratory animal facility.

4. Write a short note on
   a) Standard Operating Procedure
   b) Batch Manufacturing Record
5. Write in detail about in-process quality control (IPQC) tests of
   a. Tablets
   b. Parenterals
6. a) Describe the overview of ICH guidelines with Q series
   b) Write a short note on Calculation of yields.
7. a) Write a short note on good documentation practice guidelines.
   b) What are the different types of audits? Explain in detail audit methods and techniques involved in it.
8. Write a short note on
   a) Expiry date calculation.
   b) Copyright and trade mark.

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Code No: 8312/PCI

FACULTY OF PHARMACY
M. Pharmacy (Pharm. Quality Assurance) I- Semester (PCI) Main Examination, May 2022

Subject: Product Development and Technology Transfer

Time: 3 hours **Max Marks: 75**

Note: Answer any Five from the following questions. **(5 x 15 = 75 Marks)**

1. a. Define NDA. Explain the detailed process for filing of NDA.
   b. Define SUPAC guidelines. What is the main purpose of guidelines and explain their importance in filing process to USFDA.

2. a. Explain the significance of solubility in dosage form development and write in detail the various methods to improve solubility of poorly water soluble drugs.

   b. Enumerate the types of stability studies conducted during product development and explain the drug excipient compatibility studies.

3. a. What is a pilot plant? Explain the essential requirements and considerations for pilot plant scale up of solid dosage forms.
   b. Enlist the various type of novel drug delivery systems and explain the various opportunities that can be explored in formulation of NDDS.

4. What is the importance of container selection and quality attributes to be considered in medical devices packing.
5. a. Briefly explain the various quality control tests performed for establishing quality of containers for parenteral liquid dosage forms.

   b. Explain the significance of secondary packaging materials in pharmaceutical packaging.
6. a. What is technology transfer. Explain the various steps involved in technology transfer process.
   b. How are the various qualitative and quantitative technology models used in efficient technology transfer.

7. What is Preformulation. Write the main objective and the detailed protocol of preformulation.

8. Explain in detail the various documentation involved in technology transfer process from R &D to production.

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Code No. D-8261/PCI

FACULTY OF PHARMACY

M. Pharmacy I - Semester (Common to All) (PCI) (Main & Backlog) Examination, May 2022

Subject: Modern Pharmaceutical Analytical Techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 (a) State and explain Beer-Lambert's Law. Add a note on the deviations from Beer's law.
(b) Explain the concept of chromophore, auxochrome and bathochromic shift with suitable examples.

2 (a) Explain the instrumentation of FTIR with a neat labelled diagram. Add a note on the advantages of FTIR.
(b) Explain the mplecular vibrations in IR.

3 (a) What is the principle AAS? Explain the instrumentation.
(b) List the differences between AAS and flame photometry.

4 What is the significance of chemical shift? What are the factors affecting chemical shift? Name the internal standard and justify its selection as internal standard in NMR spectroscopy.

5 What is the principle of Mass Spectrometry? With a neat labelled diagram briefly explain the components of MS instrumentation.

6 (a) Classify the ionization techniques in MS. Explain any three methods in detail.
(b) Define Base peak, molecular ion peak and metastable ion.

7 (a) Explain the principle of X-ray diffraction.
(b) Explain HPLC instrumentation with a labelled diagram.

8 (a) Explain the experimental set up required for gel electrophoresis.
(b) Describe the principle and applications of RIA.

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Code No. E-12084/PCI

FACULTY OF PHARMACY

M. Pharmacy (Common to All) I - Semester (PCI) (Backlog) Examination, December 2022

Subject: Modern Pharmaceutical Analytical Techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) With a neat labelled diagram explain UV/Visible spectrophotometer instrumentation.
(b) What are the applications of UV spectroscopy?

2 (a) Explain the molecular vibrations in IR.
(b) Write the sampling methods in IR spectroscopy.

3 (a) Explain the principle of fluorescence.
(b) With a diagram explain the instrumentation for flame photometry.

4 (a) Explain the principle of proton NMR spectroscopy.
(b) Explain the following in NMR spectroscopy: Shielding and deshielding, chemical shift.

5 (a) Explain the principle of mass spectroscopy.
(b) Explain any two mass analysers used in MS in detail.

6 (a) Explain GC instrumentation with a labelled diagram. Add a note on the different types of GC columns.
(b) List and explain any 2 GC detectors.

7 (a) Explain Braggs equation and derive the equation.
(b) Explain the principle and types of Paper electrophoresis.

8 (a) Explain the principle and applications of ELISA?
(b) Explain the principle and applications of capillary electrophoresis.

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Code No: E-12109/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Backlog) Examination, December 2022

Subject: Quality Control and Quality Assurance

Time: 3 Hours **Max Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. Write a detailed note on requirements and guidelines of GMP (Schedule M) in pharmaceutical industry. [15]

2. Give a brief note on
   a) Non-Clinical testing. [5]
   b) Controls on animal house. [5]
   c) Distribution records [5]

3. Write in detail about in-process quality control (IPQC) tests of
   a) Tablets [8]
   b) Semisolids [7]

4. Explain common technical document (CTD) and electronic CTD. [15]

5. Describe sources of contamination and methods of contamination control. [15]

6. Write a short note on
   a) ICH guidelines with Q series [8]
   b) Aseptic process control [7]

7. Write brief note on following
   a) Change control [8]
   b) Standard operating procedures [7]

8. Write a short note on
   a) Expiry date calculation [7]
   b) Copyright and trade mark [8]

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Code No: E-12108/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Backlog) Examination, December 2022

Subject: Quality Management Systems

Time: 3 Hours **Max Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. a) What is cost of quality ? Explain models of cost of quality. [8]
   b) Write a note on OSHAS guidelines. [7]

2. a) Explain the process of NABL accreditation of a chemical testing laboratory. [8]
   b) What is Out of specification (OOS)? How is OOS handled as per USFDA guidelines. [7]

3. a) What is self-inspection ? What is its importance in quality assurance and how is it executed? [8]
   b) What is market complaining? How are they evaluated? [7]

4. a) What is stress testing? Why and how is it done? [8]
   b) How risk ranking is done? Explain in brief. [7]

5. a) Enlist and explain attribute control charts. [8]
   b) Explain the indices used for process capability. [7]

6. Explain the principles of Six sigma and writes its importance in industries. [15]

7. a) Explain the customers perception of quality. [7]
   b) Explain the elements of McKinsey 7S model. [8]

8. What is HACCP? How does it help in drug manufacturing? [15]

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Code No: E-12110/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Backlog) Examination, December 2022

Subject: Product Development and Technology Transfer

Time: 3 Hours **Max Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. a) Define ANDA. Explain the detailed process for filing of ANDA. [7]
   b) Define the various product registration guidelines of CDSCO. [8]

2. a) Explain the significance of co solvents and surfactants in improving solubility of poorly water soluble drugs. [8]
   b) Write about the different types of chemical stability studies conducted during product development . [7]

3. a) What is scale up process? Explain the various considerations for pilot plant scale up of semi-solid dosage forms. [10]
   b) How did the innovative processes influence the discovery and development of new era of drug products, explain the challenges incurred during development. [5]

4. a) Explain the importance of container selection and quality attributes to be considered in aseptic packaging systems. [8]
   b) Briefly describe the various issues faced during modern drug packaging systems in product development. [7]

5. a) Explain the various quality control tests conducted for checking quality of containers for enteral packaging. [10]
   b) Explain the significance of quality considerations for closures in pharmaceutical packaging. [5]

6. a) How does technology transfer occur in pharmaceutical industries? Explain the importance and requirements for technology transfer process. [8]
   b) Technology development by R&D is a dynamic process, write about the essential features of it. [7]

7. How does preformulation studies help the formulator in drug development? [15]

8. Write the significance of BACPAC and SNDA in drug registration process. [15]

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