Enrollment No……

Master of Pharmacy (Quality Assurance)
First Semester Main Examination, Dec-2020
Modern Pharmaceutical Analytical Techniques (MQA-101T)

Time: 3:00 Hrs **Max Marks 75**

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

Q.1 **(a) Describe the principle of UV Spectrophotometers and discuss double beam Spectrophotometer with neat diagram.**
(b) Define fluorescence. Explain the principle & instrumentation of specetroflourimetry.

Q.2 **(a) Discuss various ionization techniques used in mass Spectroscopy.**
(b) Explain the terms:
i) Chemical Shift **ii) Spin-Spin Coupling**

Q.3 **(a) Explain the fragmentation rules of organic compounds by mass spectroscopy in details.**
(b) Write a note on $_{13}C$ NMR.

Q.4 **(a) Discuss the principle, instrumentation and application of FTIR.**
(b) Discuss the principle, instrumentation and application of Flame Emission Spectroscopy.

Q.5 **(a) Write a brief account on TGA.**
(b) Discuss the principle, instrumentation and application of gel electrophoresis.

Q.6 **(a) Write an account on Bragg's Law and x-ray powder diffraction.**
(b) Explain the principle of high performance liquid chromatography. Write an account on detectors used in HPLC.

Q.7 **(a) Discuss the various modes of molecular vibrations. Explain the factors affecting vibrational frequencies of IR Spectroscopy.**
(b) Write a short note on Mclafferty rearrangement and its significance in structural diagnosis.

Q.8 **(a) Discuss principle of gas chromatography and explain any two detectors used in it.**
(b) Explain the principle, working and instrumentation of potentiometers.

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First Semester Examination, Dec-2020

Quality Management System (MQA102T)

Time: 3:00 Hrs **Max Marks 75**

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

Q.1 **(a)** Explain Quality & its objectives in detail.
(b) Explain McKinsey 7s Model in brief.

Q.2 **(a)** Write brief note on TQM.
(b) Explain Pharmaceutical Quality Management as per ICH Q-10 guidelines.

Q.3 **(a)** Explain Six System Inspection model in QMS.
(b) Write notes on Out of Specifications (OOS) & Out of trends (OOT).

Q.4 **(a)** Explain complaints of Pharmaceutical products. How the root cause can be investigated & determine.
(b) Explain steps involve in returned and recalled products.

Q.5 **(a)** Define druge stability. Explain the ICH guidelines for stability testing of drug substance & drug products.
(b) Explain quality risk management with reference to ICH-Q9 guidelines.

Q.6 **(a)** Write advantages, disadvantages & applications of statistical process control.
(b) Explain statistical control chart in detail.

Q.7 **(a)** Explain types, advantages & disadvantages of Benchmarking.
(b) Write a note on HACCP.

Q.8 **(a)** Define Vendor. Explain vendor qualification in detail.
(b) Explain IPQC of Tablets.

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First Semester Main Examination, Dec-2020

Quality Control and Quality Assurance (MQA 103T)

Time: 3:00 Hrs **Max Marks 75**

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

Q.1 **(a)** Discuss IPQC and finished products QC for Surgical products as per IP.
(b) Enlist advantages and utility of batch manufacturing record.

Q.2 **(a)** High light the defects of cGMP guidelines.
(b) Enumerate PIC, WHO and CBER covering.

Q.3 **(a)** Elaborate GMP guidelines.
(b) Discuss concept of ICH guidelines

Q.4 **(a)** Discuss analysis of raw materials, finished products, packaging materials in IPQC.
(b) Discuss developing specification as per ICH Q6 and Q3.

Q.5 **(a)** Discuss principle and steps involved in three tier documentation.
(b) Elaborate concepts of controlled and uncontrolled documents.

Q.6 **(a)** Discuss the steps and advantage of handling waste and scrop disposal.
(b) Define deviation. Discuss methodology of process deviation.

Q.7 **(a)** Define expiry date. Enlist expiry date calculation.
(b) Elaborate change control in Quality assurance.

Q.8 **(a)** Discuss scope and importance of intellectual property rights.
(b) Discuss concept of trade mark, copyright and patents.

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Master of Pharmacy (Quality Assurance)

First Semester Examination, Dec-2020

Product Development and Technology Transfer (MQA104T)

Time: 3:00 Hrs **Max Marks 75**

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

Q.1 (a) Describe quality control test of containers and closure.
(b)Write Detail note on selection and evaluation of pharmaceutical packaging material.

Q.2 (a) Elaborate concept, design and layout of pilot plant scale up study.
(b) Describe in detail manufacturing techniques at large scale.

Q.3 (a) Explain development report and technology transfer plan.
(b) Explain new era of drug products opportunities and its challenges.

Q.4 (a) Describe in detail product development guideline.
(b) Discuss development and information content for IND.

Q.5 (a) Explain techniques used for the study of crystal properties and polymorphism.
(b) Describe concept of organoleptic properties, purity and impurity in preformulation study.

Q.6 (a) Discuss qualitative and quantitative technology models. (Technology transfer).
(b) Describe in detail bulk active chemical post approval changes.

Q.7 Write short note in (Any two)-
(a) Co-Solvent
(b) Surfactants
(c) Preformulation protocols