Enrollment No…….

Master of Pharmacy (Quality Assurance)
Second Semester Examination, June-2021
Hazards and Safety Management [MQA201T]

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

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

Q.1 (a) Explain Multidisciplinary nature of environmental studies.
(b) Process of hazard management.

Q.2 (a) Critical training for risk management
(b) Define ICH guidelines on risk assessment

Q.3 (a) Write method of Risk management and Tools.
(b) Explain Factory act and rules, fundamentals of accident prevention.

Q.4 (a) Write note onNatural Resources, Renewable ,non-renewable resources.
(b) Explain the following resorces a) Forest resources; b) Water resources.

Q.5 (a) What do you mean by sterile area and non sterile area, Preliminary Hazard
(b) Write a detail note on Management of over-Exposure to chemicals and TLV concept.

Q.6 (a) Detail account on Fire and Explosion.
(b) Explain elements of safety programme and safety management.

Q.7 (a) Discuss Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Explain Safety and hazards regulations,
(b) Explain Fire protection system: prevention, types of fire extinguishers.

Q.8 Write short note on
(a) Hazard and risk management.
(b) Self-protective measures against workplace hazards.

Q.9 (a) Explain Physicochemical measurements of effluents,BOD, COD,
(b) Determination of some contaminants, Effluent treatment procedure.

Enrollment No…….

Master of Pharmacy (Quality Assurance)
Second Semester Examination, June-2021
Pharmaceutical Validation [MQA202T]

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

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

Q.1 (a) Explain Validation of Utility systems: Pharmaceutical water system & pure steam
(b) Explain HVAC system and its validation

Q.2 (a) What is the main of Compressed air and nitrogen in pharma industry
(b) Write the concept of process validation.

Q.3 (a) Explain in detail the Process and documentation of Process Validation.
(b) What do you mean by prospective, Concurrent & Retrospective Validation.

Q.4 (a) Explain the Re validation criteria, Process involved in it
(b) Write about the Validation of various formulations (Coated tablets, Capsules, Ointment/Creams.)

Q.5 (a) Write about in brief liquid Orals and aerosols., Aseptic filling: Media fill validation,
(b) Write short note on USFDA guidelines.

Q.6 (a) What is on Process Validation- A life cycle approach?
(b) Give analytical method validation: General principles, Validation of analytical method as per ICH guidelines (Q2) and USP.

Q.7 (a) Explain cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning,
(b) Write short note on following
(i) Cleaning of Equipment.
(ii) Cleaning of Facilities.

Q.8 (a) Explain in detail Cleaning in Equipment
(b) Explain the Validation of facilities in sterile and non-sterile plant.

Enrollment No…….

Master of Pharmacy (Quality Assurance)
Second Semester Examination, June-2021
Audits and Regulatory Compliance [MQA203T]

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

Note: (i) Attempt any five questions.
(ii) All questions carry equal marks.

Q.1 (a) What is the the importance of auditing in pharmaceutical industries.
(b) Write the brief note on auditing report.

Q.2 (a) Write prepareation of check list for auditing.
(b) Give Objectives of Management of audit, Responsibilities, Planning process,

Q.3 (a) Write information gathering, administration, Classifications of deficiencies.
(b) Which Role play quality systems and audits in pharmaceutical manufacturing environment.

Q.4 Write short on following:-
(a) Explain Quality systems approach Management
(b) Explain about Manufacturing operations, Evaluation activities quality system.

Q.5 (a) What do you mean by Transitioning to quality system approach.
(b) Give the Audit checklist for drug industries.

Q.6 (a) Explain about Auditing of vendors and production department.
(b) Bulk Pharmaceutical Chemicals and packaging material Vendor audit.

Q.7 (a) Auditing in Warehouse and weighing, Dry Production:
(b) Granulation, tableting, coating, capsules, sterile production and packaging.

Q.8 (a) Give brief introduction on HVAC system ,
(b) Explain Water for Injection systems, ETP.

Enrollment No……

Master of Pharmacy (Quality Assurance)
Second Semester Examination, June-2021
Pharmaceutical Manufacturing Technology [MQA204T]

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

Note : (i) Attempt any five questions.
(ii) All questions carry equal marks.

Q.1 (a) Write the manufacturing flowchart of small volume parentral (SVP) and the in process quality control test for the same?
(b) What are the in process quality control test for suspension and manufacturing flowchart of suspension?

Q.2 (a) Write the principle, process and equipment used in Lyophilisation technology?
(b) Write a detail note on advanced sterile manufacturing technology?

Q.3 (a) Write a note on process atomization in pharmaceutical industry with specific reference to manufacturing of sterile semisolids?
(b) Write a note on process atomization in pharmaceutical industry with specific reference to manufacturing of small volume parenterals and large volume parenterals?

Q.4 (a) Write a short note on any two: A. Cleaning in place B. Sterilization in place C. Form Fill Seal Technology.
(b) Write in detail about in process quality control tests for compressed tablets and the manufacturing flowcharts of the same?

Q.5 (a) Write in detail about in process quality control tests for coated tablets and the manufacturing flowcharts of the same?
(b) Write in detail about in process quality control tests for hard gelatine capsule and the manufacturing flowcharts of the same?

Q.6 (a) Write in detail about in process quality control tests for soft gelatine capsule and the manufacturing flowcharts of the same?
(b) What are the legal requirements for the development of Pharmaceutical industry?

Q.7 (a) What are the factors influencing the Plant layout and the legal requirements for the sterile and aseptic area layout?
(b) Write a short note on general principles of Production planning and the production system?

Q.8 (a) Define Quality by design. Why QbD is required, its advantages and elements of QbD?
(b) Explain the terms: A. QTPP B. CMA C. CQA D. CPP E. RLD