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PPM—08—2025

FACULTY OF SCIENCE & TECHNOLOGY

M.Pharmacy (First Year) (Second Semester) EXAMINATION

JUNE, 2025

HAZARDS AND SAFETY MANAGEMENT

Paper MQA 201 T

(Wednesday, 18-06-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Answer to the point only.

(*iii*) Figures to the right indicate full marks.

1. Solve the following questions : 10×2=20

(*a*) Enlist sources of chemical hazards.

(*b*) How accidents at workplace can be avoided ?

(*c*) What are radioisotopes based hazards ?

(*d*) Define BOD and COD.

P.T.O.

(e) Quote types of fire extinguishers.

(f) Write about hazards of organic synthesis.

(g) What are combustible gases ? Give examples.

(h) Suggest ways to mitigate chemical hazards.

(i) What are multiphase reactions ?

(j) Enlist regulations governing chemical hazards.

2. Solve any *two* of the following. 2×10=20

(a) Discuss in detail about Preliminary Hazards Analysis (PHA).

(b) Discuss in detail hazards based on air and water.

(c) Write in detail about self-protective measures against workplace hazards.

3. Solve any *seven* of the following : 7×5=35

(a) What is critical training for risk management ?

(b) Write in detail about factory act and rules.

(c) Write a note on Thermal hazards.

(d) Write about management of oxygen displacing gases and toxic gases.

(e) Write about problems associated with natural resources.

(*f*) Write about role of producers, consumers and decomposers in the ecosystem.

(*g*) What is critical hazard management system ?

(*h*) Discuss in detail about mechanical and chemical explosions.

(*i*) Discuss in detail mineral resources.

This question paper contains 2 printed pages]

PPM—20—2025

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharm (First Year) (Second Semester) EXAMINATION

JUNE, 2025

PHARMACEUTICAL VALIDATION

Paper-MQA202T

(Friday, 20-06-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— *All* questions are compulsory.

1. Answer the following questions : 10×2=20

(1) Define calibration and validation.

(2) Enlist various parameters of HPLC.

(3) Write a note on Re-qualification.

(4) Define IPR

(5) Give the difference between calibration and validation.

(6) Write a short note on patent infringement.

(7) Write a short note on SAT.

(8) What is ICH ? Give its function.

(9) Define OQ and PQ.

(10) Define revalidation. Give the types of validation.

P.T.O.

2. Solve any *two* of the following : 2×10=20

(1) Define process validation. Explain the process validation of capsules.

(2) Describe the method validation parameters for a new analytical method as per ICH guidelines.

(3) Define qualification. Explain different phases of qualification process of analytical equipment.

3. Solve any *seven* of the following : 7×5=35

(1) What is FAT ? Write its importance.

(2) What is CIP and how is it carried out ?

(3) Write a brief note on 21 CFR Part-II.

(4) Write a note on validation master plan.

(5) How Indian patent is field ? Write detailed procedure.

(6) Write a note on Media Fill validation.

(7) How will you qualify dissolution test apparatus ? Explain.

(8) Write a detailed note on computer system validation.

(9) Write a short note on process validation of coated tablets.

This question paper contains 2 printed pages]

PPM—32—2025

FACULTY OF SCIENCE & TECHNOLOGY

M. Pharmacy (Second Semester) EXAMINATION

JUNE, 2025

AUDITS AND REGULATORY COMPLIANCE

MQA-203T

(Monday, 23-06-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Answer to the point only.

(*iii*) Figures to the right indicate full marks.

1. Solve the following : 10×2=20

(*a*) Define Audit.

(*b*) What is quality system approach ?

(*c*) Enlist *four* regulatory agencies in the world.

(*d*) What is CGMP ?

(*e*) Enlist objectives of audit.

(*f*) Give the duties and responsibilities of quality auditor.

(*g*) What is critical system ?

P.T.O.

(*h*) What is HVAC ?

(*i*) What is clean room ?

(*j*) Give advantages of technology transfer.

2. Solve any *two* of the following : 2×10=20

(*a*) Explain audit process in dry production area.

(*b*) Discuss process of audit in microbiological laboratory.

(*c*) Discuss HVAC system in pharmaceutical industry.

3. Solve any *seven* of the following : 7×5=35

(*a*) Explain management responsibilities in audit process.

(*b*) Discuss role of ETP in pharmaceutical industry.

(*c*) What is external audit ? Discuss audit questionary for solid oral department.

(*d*) Discuss CGMP in pharmaceutical industry.

(*e*) Discuss audit for water for injection.

(*f*) Discuss audit for granulation department.

(*g*) Discuss audit process for quality assurance and engineering department.

(*h*) Explain quality assurance function.

(*i*) Discuss the steps in planning and corrective actions of an audit.

This question paper contains 3 printed pages]

PPM—44—2025

FACULTY OF SCIENCE & TECHNOLOGY

M. Pharm. (First Year) (Second Semester)

EXAMINATION JUNE, 2025

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

MQA204T

(Wednesday, 25-06-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Figures to the right indicate full marks.

1. Answer the following questions : 10×2=20

(*a*) Give the principle of aseptic process technology.

(*b*) What are the tools used under PAT to control quality ?

(*c*) Enlist the problems encountered in coating technology.

(*d*) What are the elements of QbD ?

(*e*) Distinguish between SVP and LVP.

(*f*) Write the role of rota granulators.

P.T.O.

(*g*) Recite various types of plastic used in packaging.

(*h*) Give the principle of aseptic process technology.

(*i*) Enlist the license required for API industry.

(*j*) Enlist the problems occurred as tablet defect in coating technology.

2. Answer any *two* of the following : 2×10=20

(*a*) Explain in detail sterile product manufacturing technology in view of area planning and environmental control, change room, utilities, engineering and maintenance.

(*b*) Describe quality control of packaging material and filling equipment as well as evaluation of stability of packaging material.

(*c*) Discuss manufacturing flow chart and IPQI test for tablets.

3. Answer any *seven* of the following : 7×5=35

(*a*) Explain aseptic process technology in suspension and emulsion.

(*b*) Discuss QbD approach for excipients.

(*c*) Describe different kinds of sealing techniques in pharmaceutical industry.

(*d*) Write the procedure for dispatching of records and scheduling.

(*e*) Write in detail about design space and control space in QbD principles.

(*f*) Explain form fill seal technology (FFS).

(*g*) Discuss in detail equipments used in parenteral manufacturing.

(*h*) Explain spheronizers and marumerisers in non-sterile manufacturing process technology.

(*i*) Describe process automation in manufacturing of sterile semisolids.