This question paper contains **3** printed pages]

TT—08—2024

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

M. Pharm. (Second Semester) EXAMINATION

APRIL/MAY, 2024

HAZARDS AND SAFETY MANAGEMENT

Paper MQA-201-T

(Wednesday, 15-05-2024) **Time : 2.00 p.m. to 5.00 p.m.**

Time—Three Hours *Maximum Marks*—75

Note :— (*i*) *All* questions are compulsory.

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

(*iii*) Answer to the point only.

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

(*a*) Mention types of fire extinguishers.

(*b*) Give the functions of ecosystem.

(*c*) What are the risk associated with sulphonation ?

(*d*) Give objectives of critical training for risk management.

(*e*) Write an importance of sprinkling and relief valves.

P.T.O.

(*f*) What do you mean by TLV ?

(*g*) What are BOD and COD ?

(*h*) Enlist various tools used to prevent hazards in industry.

(*i*) Define ecosystem.

(*j*) What is preliminary hazard analysis ?

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

(*a*) Discuss in detail about sources and controlling measures of chemical hazards.

(*b*) Explain ICH guidelines on risk management and risk assessment.

(*c*) Define and classify air pollutant. What are the sources of air pollutants ? Discuss common air pollutants in detail.

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

(*a*) Explain preventive and protection management strategy for fire and explosion hazards.

(*b*) Write in brief about management of combustible and toxic gases.

(*c*) What are the sources of chemical hazards ?

(*d*) Write a note on safety and hazard regulatory bodies.

(*e*) Discuss about role of emergency services in hazard management.

(*f*) Explain in brief multiphase reaction, transport effect and a global rates under fire and explosion.

(*g*) Describe in detail about Effluent Treatment Procedure (ETP).

(*h*) Write a note on air based hazards.

(*i*) Explain in detail cycle of nuclear fuel.

This question paper contains 3 printed pages]

TT—20—2024

FACULTY OF SCIENCE AND TEHCNOLOGY

M. Pharmacy (Second Semester) EXAMINATION

APRIL/MAY, 2024

PHARMACEUTICAL VALIDATION

(MQA-202-T)

(Friday, 17-05-2024) **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. Attempt the following : 10×2=20

(*a*) Define qualification with example

(*b*) Write the difference between validation and calibration

(*c*) What is LOD and LOQ

(*d*) Define cleaning validation

(*e*) What is mechanism of dry heat sterilization ?

(*f*) How HPLC separates mixture into its components ?

P.T.O.

(*g*) Differentiate between disintegration and dissolution.

(*h*) What is HVAC ?

(*i*) Define retrospective validation and revalidation.

(*j*) What is GAMP ?

2. Attempt any *two* : 2×10=20

(*a*) Write the concept of intellectual property and intellectual property rights.

(*b*) Explain qualification of tablet punching machine.

(*c*) Define validation and briefly explain about user requirement specifications and change managements.

3. Attempt any *seven* : 7×5=35

(*a*) Write a note on validation master plan.

(*b*) Discuss about the calibration of UV-visible spectrophotometer.

(*c*) Write steps to be followed in cleaning of equipments.

(*d*) Explain the validation of compressed air and nitrogen.

(*e*) Describe USFDA guidelines on process validation.

(*f*) Explain various paramaters of validation of analytical methods as per ICH guidelines.

(*g*) Describe types of patent application.

(*h*) Discuss significance of transfer of technology.

(*i*) Write a note on qualification of beakers and burette.

This question paper contains **3** printed pages]

TT—32—2024

FACULTY OF PHARMACEUTICAL SCIENCE & TECHNOLOGY

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

APRIL/MAY, 2024

AUDIT AND REGULATORY COMPLIANCE

Paper MQA-203T

(Monday, 20-05-2024) **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. Answer *all* the following questions : 10×2=20

(*a*) Define audit.

(*b*) Define CGMP.

(*c*) What is GMP audit ?

(*d*) Enlist different stages in audit.

P.T.O.

(*e*) Name different regulatory agencies.

(*f*) Write information gathering process for audit.

(*g*) What is quality system approach ?

(*h*) Enlist design and construction features of water for injection.

(*i*) Write difference between critical and non-critical components.

(*j*) Define quality control.

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

(*a*) Explain role of quality system in manufacturing.

(*b*) Describe procedure to perform audit for micro-biological laboratory.

(*c*) Discuss audit in bulk pharmaceutical industry.

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

(*a*) What are evaluation activities for drug industries ? Describe in detail.

(*b*) Describe audit in granulation.

(*c*) Explain audit cheaklist for drug industries.

(*d*) Explain audit of HUAC system.

(*e*) Discuss on quality assurance maintenance.

(*f*) Discuss vendor audit.

(*g*) Explain audit in engineering department.

(*h*) Discuss various CGMP regulations for pharma industry.

(*i*) What is role of ETP in industry ?

This question paper contains **3** printed pages]

TT—44—2024

FACULTY OF PHARMACEUTICAL SCIENCE & TECHNOLOGY

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

APRIL/MAY, 2024

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Paper MQA-204T

(Wednesday, 22-05-2024) **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. *All* questions are compulsory : 10×2=20

(*a*) What is QTPP ?

(*b*) Give the principle of non-sterile manufacturing technology.

(*c*) What is CIP ?

(*d*) Enlist quality control test for container and closures.

(*e*) What are the factors affecting plant layout ?

P.T.O.

(*f*) What is process automation in pharmaceutical industry ?

(*g*) Give application of fluidized bed technology.

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

(*i*) What do you mean by flexible packaging ?

(*j*) Give the benefits of PAT.

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

(*a*) Explain in detail the IPQC test for tablets and capsules.

(*b*) Describe in detail lyophilization technology.

(*c*) Discuss QBD approach for drug substance.

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

(*a*) Discuss problems encountered during coating process.

(*b*) Explain IPQC test for sterile emulsion and suspension.

(*c*) Describe in detail equipments used in tablet and capsule manufacturing.

(*d*) Explain tools of PAT.

(*e*) Discuss manufacturing technology of SVP and LVP.

(*f*) Explain importance of training in pharmaceutical industry.

(*g*) Give the factors influencing plant location.

(*h*) Explain applications and benefits of prefilled syringe.

(*i*) Discuss the stability aspects of packaging.

This question paper contains **3** printed pages]

QT—37—2023

FACULTY OF SCIENCE AND TECHNOLOGY

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

JANUARY, 2024

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Paper MQA-204T

(Wednesday, 3-1-2024) **Time : 2.00 p.m. to 5.00 p.m.**

Time—Three 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. Answer all the following questions : 10×2=20

(*a*) Enlist the quality control tests for containers and closures.

(*b*) Give wall and floor treatment of sterile product manufacturing area.

(*c*) What is meant by sterilization in place (SIP) ?

(*d*) Write in short about Rota granulator.

P.T.O.

(e) Write importance of blister pack in pharmaceutical packaging.

(f) Enlist different factors considered while selecting plant layout.

(g) Write Pyrogen test for injectables.

(h) What is QTPP ?

(i) Compare continuous and batch mixing in tablet production.

(j) What is form fill seal technology ?

2. Long answer questions (answer **2** out of 3) : 2×10=20

(a) Explain in detail production planning.

(b) Discuss in detail manufacturing, manufacturing flow chart and IPQC test for sterile emulsion and suspension.

(c) Describe in detail quality by design approach.

3. Short answer questions (answer **7** out of 9) : 7×5=35

(a) Explain sterile product manufacturing technology in view of area planning and environmental control, wall and floor treatment.

(b) Write in detail manufacturing flow chart and IPQC test for Tablets.

(c) Discuss in detail coating equipments.

(d) Describe in short spheronizers and marumerisers along with their advantages.

(*e*) Explain PAT Act as a driver for improving quality and reducing cost.

(*f*) Describe principle and process for Lyophilization technology.

(*g*) Explain in detail biological test for containers and closures.

(*h*) Write a short note on analytical QbD.

(*i*) Write notes on :

(*a*) Calculation of standard cost

(*b*) Dispatching of records.

This question paper contains 2 printed pages]

HQ—17—2022

FACULTY OF SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2023

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA202T

(Pharmaceutical Validation)

(Monday, 20-3-2023) **Time : 2.00 p.m. to 5.00 p.m.**

Time—Three 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 all of the following : 10×2=20

(*a*) What are FAT and SAT ?

(*b*) Define preventive maintenance.

(*c*) What is operational qualification ?

(*d*) Give applications of HPTLC.

(*e*) Differentiate between validation and calibration.

(*f*) What is copyright ?

(*g*) What is clean room ?

(*h*) Write advantages of equipment qualification.

(*i*) Enlist quality control test for coated tablets.

(*j*) What is intellectual property ?

P.T.O.

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

(*a*) Define compressed air system. Explain validation of compressed air system.

(*b*) Explain various steps involved in cleaning validation.

(*c*) Discuss qualification of UV-visible spectrophotometer

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

(*a*) Discuss validation of media fill test.

(*b*) Enlist different IPR. Explain patent and trademarks.

(*c*) Explain computer system validation.

(*d*) Describe process validation technique in detail.

(*e*) Explain the steps involved in designing and installation of pharmaceutical water system.

(*f*) Describe the process of copyright registration.

(*g*) Explain various parameters as per ICH in method validation.

(*h*) Discuss qualification of disintegration test apparatus.

(*i*) Explain validation of capsule filling machine.

This question paper contains 2 printed pages]

HQ—07—2022

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2023

HAZARD AND SAFETY MANAGEMENT

Paper-MQA-201-T

(Friday, 17-03-2023) **Time : 2.00 p.m. to 5.00 p.m.**

Time— Three Hours *Maximum Marks—75*

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

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

1. Write the answer of the following : 10×2=20

(*a*) Why is TLV important ?

(*b*) What is an ecosystem ?

(*c*) Write an importance of sprinkling and relief valves.

(*d*) Mention sources responsible to create bad air quality.

(*e*) Write the significance to minimize the use of non-renewable energy resources.

(*f*) Which gas is used in fire extinguisher ?

(*g*) What are the two different hazards of electricity ?

(*h*) Give the significance of critical hazard management system.

(*i*) Enlist various tools used to prevent hazards in industry.

(*j*) Write the role of flares.

2. Write the answer of any *two* questions : 2×10=20

(*a*) Define and classify air pollutant. What are the sources of air pollutants? Discuss common air pollutants in detail.

(*b*) Discuss the mechanical, electrical and thermal hazards to human. Discuss any *one* type of hazards in detail.

(*c*) Write about function of producers, consumers and decomposers in an ecosystem. Describe the concept of an ecosystem.

P.T.O.

3. Write the answer of any *seven* questions : 7×5=35

(*a*) What is PHA ? Discuss the key features of PHA.

(*b*) Discuss the methods used in a pharmaceutical plant for fire prevention.

(*c*) What are TLV and STEL concepts ? Explain their application for protection of workers to chemical exposure.

(*d*) Explain sulphonating hazards and their prevention.

(*e*) Classify electric hazards and methods to prevent them.

(*f*) Discuss mechanical hazards in a pharmaceutical plant and methods used for preventing them.

(*g*) Write a note on safety and hazard regulatory bodies.

(*h*) What are BOD and COD ? Write their limits for maintaining acceptable effluent quality.

(*i*) Discuss the Sprinkling and relief valves for fire control.

This question paper contains 2 printed pages]

PQ—03—2022

FACULTY OF SCIENCE & TECHNOLOGY

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

MAY/JUNE, 2022

HAZARDS & SAFETY MANAGEMENT

(MQA-201T)

(Tuesday, 26-07-2022) **Time : 02.00 p.m. to 05.45 p.m.**

Time— 3.45 *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 all the following : 2×10=20

(*a*) Give the objectives of Factory Act and Rules.

(*b*) Enlist the sources of air based hazards.

(*c*) What are the risk associated with sulphonation ?

(*d*) Enlist the renewable and non-renewable sources of energy.

(*e*) Give the functions of ecosystem.

(*f*) What is preliminary hazard analysis ?

(*g*) Mention the types of fire extinguishers.

(*h*) What is TLV ? Mention its significance.

(*i*) Enlist the hazard based on radioisotopes.

(*j*) Give the objectives of critical training for risk management.

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

(*a*) Discuss in detail about air circulation maintenance for sterile area and non-sterile area in industry.

P.T.O.

(*b*) Discuss in detail about source and controlling measures of chemical hazards.

(*c*) Discuss about energy resources and land resources and problem associated with it.

3. Solve any *seven* of the following :

(*a*) Write a note on ICH guidelines for risk assessment and management.

(*b*) Discuss various management tools to control over exposure to chemicals.

(*c*) What is the relief system and proofing system in prevention and protection of fire.

(*d*) Write in brief about management of combustible and toxic gases.

(*e*) Write a note on critical training for risk management.

(*f*) Discuss in brief about multiphase reaction, transport effect and global rates under fire and explosion.

(*g*) Write a note on natural resources.

(*h*) Write a note on air based hazards.

(*i*) Discuss about role of emergency services in hazards management.

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This question paper contains **2** printed pages]

PQ—09—2022

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharmacy (Second Semester) EXAMINATION

MAY/JUNE, 2022

(CBCS/PCI)

PHARMACEUTICAL VALIDATION

(Thursday-28-7-2022) **Time : 2.00 p.m. to 5.45 p.m.**

Time— 3.45 *Hours* *Maximum Marks*—75

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

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

1. Attempt the following : 2×10=20

(*a*) Define qualification with example.

(*b*) Write importance of Vendor Certification.

(*c*) Enlist important steps involved in disposal of Pharmaceuticals.

(*d*) What is pharmaceutical process validation ?

(*e*) Write applications of HVAC in Pharmacy.

(*f*) What is compatibility study ?

(*g*) What is the significance of critical process steps ?

(*h*) Define validation master plan.

(*i*) Define revalidation and change management.

(*j*) What is compatibility test ?

2. Solve any *two* : 10×2=20

(*a*) What do you mean by analytical method validation. How analytical method is validated as per ICH guidelines.

P.T.O.

(*b*) What is qualification of instruments ? Explain qualification of HPLC.

(*c*) Explain intellectual property, intellectual property protection and intellectual properly rights.

3. Attempt any *Seven* : 5×7=35

(*a*) Explain FAT and SAT.

(*b*) Describe different IPQC tests for Tablet formulation.

(*c*) Explain different steps of qualification for Tablet punching machine.

(*d*) Explain importance of training in Pharmaceutical.

(*e*) Explain validation of sterile product plant.

(*f*) How to control raw material in Pharma Industry.

(*g*) What is cleaning method development. Discuss cleaning in place.

(*h*) Explain role of IP in Pharmaceutical Industry.

(*i*) Describe validation of integrated lines by media fill test.

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This question paper contains **2** printed pages]

PQ—15—2022

FACULTY OF PHARMACEUTICAL SCIENCES

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

JUNE/JULY, 2022

(CBCS PSI)

AUDITS AND REGULATORY COMPLIANCE

MA203T

(Saturday, 30-7-2022) **Time : 2.00 p.m. to 5.45 p.m.**

Time— 3.45 *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 *all* the questions : 10×2=20

(*a*) Define quality audit.

(*b*) Give the types of compliance risk.

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

(*d*) Give the objectives of audit.

(*e*) Define Vendor.

(*f*) Give the advantages of management audit.

(*g*) Enlist the packaging materials used for packaging of pharmaceuticals.

(*h*) What is critical system ?

(*i*) What is HVAC ?

(*j*) Enlist the qualities of vendor selection.

P.T.O.

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

(*a*) Discuss the auditing and manufacturing process of microbiological laboratory.

(*b*) Discuss CGMP regulations in manufacturing of pharmaceuticals.

(*c*) Discuss in detail bulk pharmaceutical chemicals and packaging materials vendor audit.

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

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

(*b*) Explain the quality assurance functions.

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

(*d*) Discuss the management responsibilities of an audit.

(*e*) Discuss the audit of granulation department.

(*f*) Discuss role of quality system in manufacturing operations.

(*g*) Explain the audit of sterile product and packaging in detail.

(*h*) Discuss building raw materials, water and packaging materials in microbiology laboratory.

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

This question paper contains **2** printed pages]

PQ—21—2022

FACULTY OF PHARMACEUTICAL SCIENCES

M. Pharm. (Second Semester) EXAMINATION

MAY/JUNE, 2022

(CBCS PCI)

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

MQA204T

(Tuesday, 02-8-2022) **Time : 2.00 p.m. to 5.45 p.m.**

Time— 3.45 *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 : 20

(*a*) What is sterilization in place (SIP) ?

(*b*) What is formulation by design ?

(*c*) Enlist in process quality control tests for suspension ?

(*d*) What is QTTP ?

(*e*) State ICH guidelines.

(*f*) Write a note on drug plastic interaction.

(*g*) What is QbD ?

(*h*) What is process automation in pharmaceutical industry ?

(*i*) Write in brief about Form Fill Seal (FFS) technology.

(*j*) Give application of fluidized bed technology.

P.T.O.

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

(*a*) Explain lyophilization technology in detail.

(*b*) Discuss in details about containers and closures used for pharmaceuticals.

(*c*) Discuss process automation in pharma industries for granulation and pelletization processes.

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

(*a*) Give the quality control test for emulsion and suspension.

(*b*) Describe the legal requirement during developing a pharmaceutical industry. What are the factors influencing plant location ?

(*c*) Discuss in detail about Cleaning In Place (CIP).

(*d*) How stability of pharmaceutical packaging material is evaluated ?

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

(*f*) Discuss in detail the QbD approach for excipients.

(*g*) Discuss in detail factors affecting plant layout.

(*h*) Discuss in detail various tools of Process Analytical Technology (PAT).

(*i*) Discuss the problems encountered in coating process.

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This question paper contains **2** printed pages]

CN—03—2019

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

OCTOBER/NOVEMBER, 2019

HAZARDS OF SAFETY MANAGEMENT

(MQA-201T)

(Thursday, 28-11-2019) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) Attempt all questions.

(*ii*) *All* questions carry equal marks.

(*iii*) Answer to the point only.

1. Answer any *ten* : 10×2=20

(*a*) Give the classification of mineral sources with examples.

(*b*) Mention the types of fire extinguishers.

(*c*) What is BOD and COD ?

(*d*) List out the significance of ecosystem.

(*e*) Name the categories of biotic compounds.

(*f*) What is preliminary hazard analysis ?

(*g*) Enlist hazard based on radioisotopes.

(*h*) What is TLV ? Mention its objectives.

(*i*) Define ecosystem.

(*j*) Mention the non-renewable and renewable sources of energy.

(*k*) Enlist the risk due to sulphonation.

(*l*) Write the effect of mining on environment.

P.T.O.

2. Answer any *two* : 2×10=20

(*a*) Give the ICH guidelines on risk management and risk assessment.

(*b*) Describe in brief about water pollution. How is it controlled ?

(*c*) Discuss the role of emergency services to prevent any hazard.

3. Answer any *seven* : 7×4=28

(*a*) Describe how to control measures for chemical hazards ?

(*b*) Explain preventive and protection management strategy for fire and explosion hazards.

(*c*) Discuss in detail critical hazard management system.

(*d*) Discuss on the fundamentals of accident prevention in industry.

(*e*) Explain in detail cycle of nuclear fuel.

(*f*) How hazards can be identified ?

(*g*) Write in brief multiphase reaction, transport effect and global rates under fire and explosion.

(*h*) What are the sources of chemical hazards ?

(*i*) Explain various natural resources and their associated problems.

This question paper contains **2** printed pages]

CN—09—2019

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

OCTOBER/NOVEMBER, 2019

PHARMACEUTICAL VALIDATION

(MQA-202-T)

(Saturday, 30-11-2019) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) Attempt *All* questions.

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

(*iii*) Answer to the point only.

1. Attempt any *ten* : 10×2=20

(*a*) What are trademarks ?

(*b*) What is validation master plan ?

(*c*) Write ethics in patenting.

(*d*) Define and classify intellectual property right.

(*e*) Differentiate between copyright and trademark.

(*f*) Define validation and qualification.

(*g*) What is PCT ?

(*h*) Define the term Validation and give is types.

(*i*) Give the criteria for patentable inventions in India.

(*j*) Define cleaning validation.

(*k*) USFDA guidelines for process validation.

(*l*) Re-validation criteria for process validation.

P.T.O.

2×10=20

2. Answer the following (any *two*) :

(*a*) List out different IPR. Write in detail about copyright registration.

(*b*) What do you mean by analytical method validation ? How analytical method is validated as per ICH guidelines ?

(*c*) Describe in detail about cleaning validation of tablet punching machine.

7×5=35

3. Answer the following (any *seven*) :

(*a*) Explain the procedures of patenting in India.

(*b*) How validation of process is carried out ? Explain.

(*c*) Write in detail about Ethics in IPR.

(*d*) Why trademark is it important ? Give the process of registration of trademark.

(*e*) Give stepwise approach of commercialization of a patent.

(*f*) Explain in detail about FAT and SAT.

(*g*) Explain different stages of capsule filling machine qualification.

(*h*) Explain validation of sterile product plant.

(*i*) State the importance of electronic record of validation of it.

This question paper contains **2** printed pages]

CN—15—2019

FACULTY OF SCIENCE AND TECHNOLOGY

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

OCTOBER/NOVEMBER, 2019

PHARMACEUTICAL QUALITY ASSURANCE

(Audits and Regulatory Compliance MQA 203T)

(Tuesday, 3-12-2019) **Time : 2.00 p.m. to 5.00 p.m.**

Time— Three Hours *Maximum Marks*—75

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

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

(*iii*) Answer to the point only.

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

(*a*) Give advantages of audit.

(*b*) What is DOP test ?

(*c*) What is clean room ?

(*d*) Give advantages of technology transfer.

(*e*) What is self inspection ?

(*f*) What is information gathering.

(*g*) Enlist the quality assurance functions.

(*h*) What is bacteriostatic water for injection ?

(*i*) Why is GMP important in pharmaceutical industry ?

(*j*) Enlist inprocess quality control test for capsules.

(*k*) Give the importance of record keeping.

(*l*) Define Vendor audit.

P.T.O.

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

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

(*b*) Discuss HVAC system in Pharmaceutical industry.

(*c*) Describe the process of audit in microbiological laboratory.

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

(*a*) Explain role of ETP in pharma industry.

(*b*) Explain the procedure to perform audit in quality control facilities.

(*c*) Discuss audit checklist for active pharmaceutical ingredient industry.

(*d*) What is compliance audit ? Explain benefits of compliance audit.

(*e*) Explain audit in packaging area.

(*f*) Explain CGMP in pharmaceutical industry.

(*g*) What is external audit ? Provide audit questionnaire for warehouse department.

(*h*) What is quality audit ? Explain quality audit process.

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

This question paper contains **2** printed pages]

CN—21—2019

FACULTY OF SCIENCE & TECHNOLOGY

M.Pharam (First Year) (Second semester) EXAMINATION

OCTOBER/NOVEMBER, 2019

PHARMACEUTICAL QUALITY ASSURANCE

(MQA 204-T)

(Pharmaceutical Manufacturing Technology)

(Thursday, 5-12-2019) **Time : 2.00 p.m. to 5.00 p.m**

Time— Three 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. Answer *all* the questions : 10×2=20

(*a*) What is QTPP ?

(*b*) Write objectives of pelletization.

(*c*) Give the benefits of PATS.

(*d*) What is meant by routing and loading ?

(*e*) Enlist process automation technology used in pharmaceutical industry.

(*f*) Write importance of area planning and environment control in sterile product Manufacturing Technology.

(*g*) What do you mean by flexible packaging ?

(*h*) Differentiate between hard and soft capsules.

(*i*) Write various quality control tests for glass container.

(*j*) Enlist various factors influencing for plant locations.

2. Long answer type questions (Answer *two* out of three) : 10×2=20

(*a*) Discuss manufacturing technology of SVP and LVP in detail.

(*b*) Explain in detail quality control tests for containers and closures.

(*c*) What is QbD ? Explain elements and requirements of QbD for drug substances.

P.T.O.

3. Short answer type questions (solve *seven* out of nine) : 7×5=35

(*a*) Write factors affecting or influencing for plant location.

(*b*) Give the manufacturing flow-chart for dry powder and ointment.

(*c*) Explain application and benefits of prefilled syringe.

(*d*) Write the stability aspects of packaging materials.

(*e*) Comment on sterile and aseptic area layout

(*f*) Explain problem encountered while coating of tablets.

(*g*) Write notes on :

(*i*) Calculation of standard cost.

(*ii*) Dispatching of records.

(*h*) Explain in brief different tools of PAT.

(*i*) Discuss IPQC tests for tablet.

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This question paper contains 2 printed pages]

CM—03—2019

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M. Pharmacy (Second Semester) EXAMINATION

MARCH/APRIL, 2019

HAZARD AND SAFETY MANAGEMENT

(MQA-201T)

(Tuesday, 23-4-2019) **Time : 2.00 p.m. to 5.00 pm**

Time—3 *Hours* *Maximum Marks*—75

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

(*ii*) Answer to the points only.

1. Solve any *ten* : 10×2=20

(*a*) Write the benefits of non-renewable resources.

(*b*) What are the problems faced by industry by land resources ?

(*c*) What are the rules to manage hazard and risk due to dust ?

(*d*) What is significance for understading problems faced by air ?

(*e*) Enlist various renewable and non-renewable sources in nature.

(*f*) What is Ecosystem ?

(*g*) Enlist solvent names which create risk hazards.

(*h*) Give the types of fire extinguishers.

(*i*) Enlist various tools used for risk managment as per ICH guideline.

(*j*) Write factory act related to hazard in two lines.

(*k*) Write the importance of critical training for risk management.

(*l*) Enlist the techniques used to prevent fire hazard.

2. Solve any *two* : 2×10=20

(*a*) Discuss the process in air circulation maintenance in industry for sterile and non-sterile area as per regulatory guidelines.

(*b*) Describe the detail management strategy for toxic gases and oxygen displacing gases.

(*c*) What are the self-protective measures should be taken against workplace hazard ? Explain critical training for risk management.

P.T.O.

3. Solve any *seven* : 7×5=35

(*a*) Describe various method of hazard assessment due to fire.

(*b*) Explain fundamental steps used to prevent accident in industry.

(*c*) Discuss fire and explosion due to multiphase reaction.

(*d*) Write the procedure used to manage combustible gases.

(*e*) Explain management techniques used to prevent air based hazards.

(*f*) Describe various methods used for effluent treatment.

(*g*) Discuss various procedures used to assess hazard due to air and water.

(*h*) Write regulations used for chemical hazard.

(*i*) Discuss various elements of safety program and safety management in hazard and risk management.

This question paper contains 2 printed pages]

CM—09—2019

FACULTY OF SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2019

(New Course)

PHARMACEUTICAL QUALITY ASSURANCE

(MQA-202-T)

(Pharmaceutical Validation)

(Thursday, 25-4-2019) **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.

(*iii*) Answer to the point only.

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

(*a*) What is FAT and SAT ?

(*b*) Differentiate between validation and qualification.

(*c*) What is media fill test ?

(*d*) What is validation master plan ?

(*e*) Enlist ICH quality guidelines.

(*f*) Discuss importance of validation in pharmaceutical Industry.

(*g*) Give applications of HPLC.

(*h*) What is cleaning in place ?

(*i*) Enlist quality control test for water for injection.

(*j*) Define preventive maintenance.

(*k*) What is compressed air ?

(*l*) List validation parameters of tablets at compression and coating stage.

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

(*a*) Explain analytical method validation as per ICH guideline.

(*b*) What is equipment qualification ? Explain the steps involved in qualification procedure.

(*c*) Discuss cleaning validation in pharmaceutical industry.

P.T.O.

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

(*a*) Explain validation of fluid bed dryer.

(*b*) What are contaminants ? How to minimize cross contamination.

(*c*) Explain process validation of Ointment and Creams.

(*d*) Discuss qualification of dissolution test apparatus.

(*e*) Explain validation of electronic records.

(*f*) Explain prospective and retrospective process validation with example.

(*g*) Discuss the steps involved in qualification of HVAC system.

(*h*) Explain validation of sterile dosage form.

(*i*) Discuss importance of training in pharmaceutical industry.

This question paper contains **2** printed pages]

CM—15—2019

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

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

NOVEMBER/DECEMBER, 2019

PHARMACENTICAL QUALITY ASSURANCE

(MQA-203-T)

(Audits and Regulatory Compliance

(Friday, 27-4-2019) **Time : 2.00 p.m. to 5.00 p.m.**

Time— Three Hours *Maximum Marks—75*

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

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

(*iii*) Answer to the point only.

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

(*a*) What are the basic objectives of audit ?

(*b*) What is cGMP ?

(*c*) Define critical system in pharmaceutical industry.

(*d*) Give difference between quality and GMP audit.

(*e*) What is information gathering ?

(*f*) Enlist quality control test parameters for tablets.

(*g*) What is regulatory audit ?

(*h*) Give the significance of microbiological studies in drug industries.

(*i*) Enlist the key elements in the manufacturing department.

(*j*) Define water for injection as per I.P.

(*k*) What is quality ?

(*l*) What are the in-process quality control test for primary padeging ?

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

(*a*) Explain the procedure to perform audits in quality control facilities.

(*b*) Discuss audit questionnaire for store department.

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

P.T.O.

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

(*a*) Explain audit process in capsule manufacturing area.

(*b*) Explain role of ETP in industry.

(*c*) Describe the process of audit in microbiological laboratory.

(*d*) Discuss the role of quality assurance in Pharmaceutical industry.

(*e*) Explain various classifications of deficiencies of audits.

(*f*) Discuss evaluation parameter of quality audit.

(*g*) Explain the auditing in engineering department.

(*h*) How to control raw materials in store department.

(*i*) Discuss the audits points in coating department.

This question paper contains 2 printed pages]

CM—21—2019

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2019

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Paper MQA-204T

(Tuesday, 30-4-2019) **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.

(*iii*) Answer to the point only.

1. Solve any *ten* : 10×2=20

(*a*) Write the benefit of PAT.

(*b*) Enlist different types of closure.

(*c*) Give the role of spheronizers and marumerisers in pharmaceutical manufacturing.

(*d*) Give the principle of lyophilization technology.

(*e*) Give the elements of QbD approach in pharmaceuticals.

(*f*) Give the benefits of process automation in pharmaceutical industry.

(*g*) Enlist the practices of aseptic process technology.

(*h*) Write the names of different types of closure liners.

(*i*) Write the name of various biological tests carried out in pharmaceuticals.

(*j*) Draw flow chart of manufacturing of dry powder.

(*k*) What are advantages of PAT ?

(*l*) What is CQA and CMA ?

P.T.O.

2×10=20

2. Solve any *two* :

(*a*) Discuss in detail QbD approach for drug product, Drug substance and excipients.

(*b*) Discuss quality control of packaging material and filling equipment.

(*c*) What are advance non-sterile solid product manufacturing technology ? Discuss tablet production process, granulation and pelletization equipments.

7×5=35

3. Solve any *seven* :

(*a*) Write various legal requirement and licences for formulation industry.

(*b*) Explain manufacturing of sterile semi solids as process automation.

(*c*) Explain various factors influencing on layout planning.

(*d*) Discuss in-process quality control test for suspension and emulsion.

(*e*) Explain various strategies implemented for wall and floor treatment in sterile product manufacturing.

(*f*) Discuss needle free injection as an automation in pharmaceutical industry.

(*g*) Explain spheronizers and marumerisers.

(*h*) Discuss evaluation techniques of packing material.

(*i*) Discuss various tools and techniques used for PAT.

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This question paper contains **2** printed pages]

CI—09—2018

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

NOVEMBER/DECEMBER, 2018

PHARMACEUTICAL QUALITY ASSURANCE

(MQA-202T)

(PHARMACEUTICAL VALIDATION)

(Friday, 7-12-2018) **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 indicates full marks.

(*iii*) Answer to the point only.

1. Solve any *ten* : 10×2=20

(*a*) Differentiate between calibration and validation.

(*b*) What do you mean by VRS ?

(*c*) Define revalidation and change management.

(*d*) Give application of HVAL system.

(*e*) What is validation master plan ?

(*f*) Write stages of qualification of manufacturing instruments.

(*g*) What is performance qualification ?

(*h*) What do you mean by vendor certification ?

(*i*) Write importance of rural keeping in pharma industry.

(*j*) Why is cleaning validation important ?

(*k*) Enlist four IPQL test for tables.

(*l*) Write ICH quality guideline.

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

(*a*) Explain the steps involved in qualification of major equipment.

(*b*) What do you mean by analytical method validation ? How is analytical method validated as per ICH guideline ?

P.T.O.

(c) Define cleaning validation. Describe in detail about cleaning validation of table punching machine.

3. Solve any *seven* : 7×5=35

(a) What are contaminants ? How to minimize cross contamination ?

(b) Explain qualification and FBO.

(c) What do you mean by FAT and SAT ?

(d) Write different stages of capsule filling machine qualification.

(e) Explain validation of sterile product plant.

(f) Explain USFDA guidelines for process validation.

(g) Explain qualification of HPLC in analytical laboratory.

(h) Describe revalidation and requalification of instruments.

(i) Explain importance of training in pharmaceutical.

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DF—09—2018

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2018

PHARMACEUTICAL QUALITY ASSURANCE

MQA202T

(Pharmaceutical Validation)

(Tuesday, 24-4-2018) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) Figures to the right indicate full marks.

(*ii*) Draw neat diagram wherever necessary.

1. All questions are compulsory (solve **10** out of 12) : 20

(*a*) Define validation of calibration.

(*b*) Enlist different types of validation.

(*c*) What is user requirement specification ?

(*d*) Define revalidation and change management.

(*e*) Classify validation of pharmaceutical process.

(*f*) Give *four* importance of cleaning validation.

(*g*) State applications of analytical method validation.

(*h*) Write in brief about ICH guidelines.

(*i*) What do you mean by revalidation process ?

(*j*) Write stages of qualification of analytical instrument.

(*k*) What is performance qualification ?

(*l*) What do you mean by validation master plan ?

2. Solve any *two* : 20

(*a*) What do you mean by analytical method validation. How analytical method is validated as per ICH guidelines.

P.T.O.

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(*b*) Define cleaning validation. Describe in detail about cleaning validation of tablet punching machine.

(*c*) Explain qualification parameters for computer system in pharmaceuticals.

3. Solve any *seven* : 35

(*a*) What do you mean by factory acceptance test and site acceptance test ?

(*b*) Write different stages of capsule filling machine qualification.

(*c*) Explain validation of sterile product plant.

(*d*) State importance of electronic record of validation of it.

(*e*) Explain USFDA guidelines for process validation.

(*f*) Explain qualification of HPLC system in analytical laboratory.

(*g*) Explain different IPQC test for tablet formulation.

(*h*) Write about re-validation criteria for process validation.

(*i*) Explain importance of training in pharmaceuticals.

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DF—03—2018

FACULTY OF PHARMACEUTICAL SCIENCES

M. Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2018

HAZARDS AND SAFETY MANAGEMENT

(MQA-201T)

(Saturday, 21-4-2018) 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.

(*iii*) Draw neat and clean diagram wherever necessary.

1. Solve any *ten* of the following : 20

(*a*) What is preliminary Hazard analysis ?

(*b*) Give the types of fire extinguishers.

(*c*) Enlist the hazard based on radioisotopes.

(*d*) What is TLV ? Give its significance.

(*e*) Enlist the sources of non-renewable and renewable sources of energy.

(*f*) Define ecosystem.

(*g*) Enlist the classes of biotic components.

(*h*) Write about air circulation maintenance in pharma industry.

(*i*) What is BOD and COD.

(*j*) What are the significance of critical training for risk management.

(*k*) Enlist the classification of mineral resources with examples.

(*l*) Write the objectives of ecosystem.

P.T.O.

20

2. Solve any *two* of the following :

(*a*) How to control measures for chemical hazards. Give the regulations for chemical hazards.

(*b*) Write ICH guidelines on risk assessment and risk management.

(*c*) Describe preventive and protective management strategy for fire and explosion hazards.

35

3. Solve any *seven* of the following :

(*a*) How hazards can be identified ?

(*b*) Explain in brief about water pollution. How is it controlled ?

(*c*) Discuss roles of emergency services to prevent any hazard.

(*d*) Discuss in brief effect of mining on the environment.

(*e*) Write in brief multiphase reactions, transport effect and global rates under fire and explosion.

(*f*) What are the sources of chemical hazards.

(*g*) Explain in detail cycle of nuclear fuel.

(*h*) Discuss in detail critical hazard management system.

(*i*) Explain various natural resources and associated problems.

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HQ—07—2022

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2023

HAZARD AND SAFETY MANAGEMENT

Paper-MQA-201-T

(Friday, 17-03-2023) **Time : 2.00 p.m. to 5.00 p.m.**

Time— Three Hours *Maximum Marks—75*

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

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

1. Write the answer of the following : 10×2=20

(*a*) Why is TLV important ?

(*b*) What is an ecosystem ?

(*c*) Write an importance of sprinkling and relief valves.

(*d*) Mention sources responsible to create bad air quality.

(*e*) Write the significance to minimize the use of non-renewable energy resources.

(*f*) Which gas is used in fire extinguisher ?

(*g*) What are the two different hazards of electricity ?

(*h*) Give the significance of critical hazard management system.

(*i*) Enlist various tools used to prevent hazards in industry.

(*j*) Write the role of flares.

2. Write the answer of any *two* questions : 2×10=20

(*a*) Define and classify air pollutant. What are the sources of air pollutants? Discuss common air pollutants in detail.

(*b*) Discuss the mechanical, electrical and thermal hazards to human. Discuss any *one* type of hazards in detail.

(*c*) Write about function of producers, consumers and decomposers in an ecosystem. Describe the concept of an ecosystem.

P.T.O.

3. Write the answer of any *seven* questions : 7×5=35

(*a*) What is PHA ? Discuss the key features of PHA.

(*b*) Discuss the methods used in a pharmaceutical plant for fire prevention.

(*c*) What are TLV and STEL concepts ? Explain their application for protection of workers to chemical exposure.

(*d*) Explain sulphonating hazards and their prevention.

(*e*) Classify electric hazards and methods to prevent them.

(*f*) Discuss mechanical hazards in a pharmaceutical plant and methods used for preventing them.

(*g*) Write a note on safety and hazard regulatory bodies.

(*h*) What are BOD and COD ? Write their limits for maintaining acceptable effluent quality.

(*i*) Discuss the Sprinkling and relief valves for fire control.

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HQ—07—2022

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2023

HAZARD AND SAFETY MANAGEMENT

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HQ—07—2022

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2023

HAZARD AND SAFETY MANAGEMENT

Paper-MQA-201-T

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Time— Three Hours *Maximum Marks—75*

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HQ—17—2022

FACULTY OF SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2023

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA202T

(Pharmaceutical Validation)

(Monday, 20-3-2023) **Time : 2.00 p.m. to 5.00 p.m.**

Time—Three 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 all of the following : 10×2=20

(*a*) What are FAT and SAT ?

(*b*) Define preventive maintenance.

(*c*) What is operational qualification ?

(*d*) Give applications of HPTLC.

(*e*) Differentiate between validation and calibration.

(*f*) What is copyright ?

(*g*) What is clean room ?

(*h*) Write advantages of equipment qualification.

(*i*) Enlist quality control test for coated tablets.

(*j*) What is intellectual property ?

P.T.O.

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

(*a*) Define compressed air system. Explain validation of compressed air system.

(*b*) Explain various steps involved in cleaning validation.

(*c*) Discuss qualification of UV-visible spectrophotometer

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

(*a*) Discuss validation of media fill test.

(*b*) Enlist different IPR. Explain patent and trademarks.

(*c*) Explain computer system validation.

(*d*) Describe process validation technique in detail.

(*e*) Explain the steps involved in designing and installation of pharmaceutical water system.

(*f*) Describe the process of copyright registration.

(*g*) Explain various parameters as per ICH in method validation.

(*h*) Discuss qualification of disintegration test apparatus.

(*i*) Explain validation of capsule filling machine.

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HQ—17—2022

FACULTY OF SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2023

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA202T

(Pharmaceutical Validation)

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P.T.O.

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