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

TT—01—2024

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M. Pharm. (First Semester) EXAMINATION

APRIL/MAY, 2024

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Paper MQA-101-I

(Tuesday, 14-05-2024) **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*) What are chromophores and auxochromes ?

(*b*) Enlist name of solvents used in NMR.

(*c*) Give the significance of isotopic peak.

(*d*) Differentiate between stationary phase of HPTLC and TLC.

P.T.O.

(*e*) What is gel electrophoresis ?

(*f*) Write application of potentiometer.

(*g*) Define quinchers with suitable examples.

(*h*) What do you mean by quantum numbers ?

(*i*) Write principle of affinity chromatography.

(*j*) Give the nitrogen rule.

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

(*a*) What is shielding and deshielding effect in NMR ? Discuss various factors influencing chemical Shift.

(*b*) Write in detail about instrumentation of UV-visible spectroscopy.

(*c*) Give principle of XRD. Discuss in detail about instrumentation of XRD.

3. Solve any *seven* : 7×5=35

(*a*) Describe sampling techniques in IR spectroscopy.

(*b*) What is chemical shift ? Explain factors influencing chemical shift.

(*c*) Explain different types of ion produced in masss pectroscopy.

(*d*) Write in detail about instrumentation of gas chromatography.

(*e*) State Bragg's law. Write types of crystal affecting X-ray diffraction result.

(*f*) Write a note on Differential Thermal Analysis (DTA)

(*g*) Explain in detail McLafferty rearrangement.

(*h*) Explain the procedure for ion exchange chromatography.

(*i*) Discuss in detail about Differential Scanning Calorimetry (DSC).

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

TT—14—2024

FACULTY OF PHARMACEUTICAL SCIENCE

M. Pharm. (First Semester) EXAMINATION

APRIL/MAY, 2024

QUALITY MANAGEMENT SYSTEM

Paper MQA-102T

(Thursday, 16-05-2024) **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. Solve all the following : 10×2=20

(*a*) Define six sigma.

(*b*) Define quality. Enlist the different dimensions of quality.

(*c*) What is difference between mission and vision ?

(*d*) Define out of specification with example.

(*e*) What is internal and external customer ?

P.T.O.

(*f*) Define TQM.

(*g*) Write in brief about classification of customers.

(*h*) Define cost of quality.

(*i*) What is cost of internal failure ?

(*j*) What is customer satisfaction and customer delight ?

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

(*a*) What is customer perception ? Write in detail about factor affecting the customer perception

(*b*) Discuss NABL certification and accrediation process.

(*c*) Write in detail about ISO 9001 : 2008.

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

(*a*) Write in detail about categories of cost of quality.

(*b*) Write in detail about six sigma and lean six sigma.

(*c*) Discuss statistical process control techniques.

(*d*) Discuss the ICH guidelines for stability testing of drug substance and drug product.

(*e*) Discuss in detail about QbD (Quality by Design)

(*f*) Discuss in detail about the change control and deviation procedure.

(*g*) Define benchmarking and discuss in detail types of benchmarking.

(*h*) Define vendor. Discuss qualification of a vendor.

(*i*) Discuss measuring process control and quality improvement.

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

TT—26—2024

FACULTY OF PHARMACEUTICAL SCIENCE

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

APRIL/MAY, 2024

QUALITY CONTROL AND QUALITY ASSURANCE

(MQA-103T)

(Saturday, 18-05-2024) **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.

(*iii*) Answer to the point only.

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

(1) Differentiate between quality control and quality assurance.

(2) Enlist IPQC tests for ointments and cream.

(3) What is three-tier documentation ?

(4) What is process deviation ?

(5) Enlist objectives behind establishing ICH guidelines.

P.T.O.

(6) Write about scope of GLP.

(7) Elaborate PDCA cycle.

(8) Give composition of IAEC.

(9) What is drug product salvaging ?

(10) What is change control ? Give its significance.

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

(1) What is quality audit ? Discuss types of audit & audit procedure in detail.

(2) Discuss cGMP guidelines according to schedule m.

(3) Elaborate structure and functions of ICH steering committee.

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

(1) Write a note on good warehousing practices.

(2) Write a note on purchase specification.

(3) Write in detail about CTD & eCTD.

(4) Discuss about the concept of regulated and non-regulated market.

(5) Discuss the scope and importance of intellectual property rights.

(6) Elaborate IPQC tests for parenterals.

(7) Discuss the measures to avoid mix-ups in pharmaceutical industry.

(8) How analysis of raw materials is carried out ?

(9) Write in detail about CPCSEA guidelines.

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

TT—38—2024

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

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

APRIL/MAY, 2024

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

Paper MQP-104T

(Tuesday, 21-05-2024) **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.

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

(*a*) What is SUPAC ?

(*b*) What is Clinical Research Process ?

(*c*) Enlist quality control test parameters for solids.

(*d*) What is post-marketing surveillance ?

(*e*) Give the importance of co-solvency.

P.T.O.

(*f*) Define optimization batch.

(*g*) What is development report ?

(*h*) Enlist issue facing by modern drug packaging.

(*i*) Explain technology transfer in pharmaceuticals.

(*j*) Define surfectant role in product development.

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

(*a*) Discuss the various problems during technology transfer from research and development to production.

(*b*) Explain types of packaging with its quality control tests.

(*c*) Describe in detail about ANDA.

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

(*a*) Explain solubility testing during product development.

(*b*) Discuss product registration guidelines of CDSCO.

(*c*) Explain preformulation protocol.

(*d*) Describe the large scale manufacturing techniques of liquid oral.

(*e*) Explain the layout of pilot plant of parenteral dosage form.

(*f*) Describe IND approval process with flow diagram.

(*g*) Explain qualitative and quantitative technology models.

(*h*) Explain advantages and disadvantages of glass containers.

(*i*) Discuss technology transfer planning and exhibition.

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

QT—01—2023

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

M.Pharm. (CSCS PSI) (First Semester) EXAMINATION

NOVEMBER/DECEMBER, 2023

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Paper MQA-101T

(Tuesday, 26-12-2023) **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.

(*iii*) Answers to the point only.

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

(*a*) State Beer's law.

(*b*) What are overtones and Fermi resonance ?

(*c*) Compare ^{13}C NMR and H^1 NMR.

(*d*) Write the principle of atomic absorption spectroscopy.

(*e*) Enlist the different regions of IR.

(*f*) What is retention factor ? Give its importance.

(*g*) Write the various detectors used in gas chromatography.

(*h*) What are quantum number ? Give its examples.

(*i*) What are important parameters of X-ray diffraction ?

(*j*) What is the process of deshielding ?

P.T.O.

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

(*a*) Write the role of UV, IR, NMR and MS in structural elucidation with suitable examples.

(*b*) Write in detail about instrumentation principle and application of HPTLC.

(*c*) Explain in brief about spin-spin coupling and chemical shift.

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

(*a*) Write instrumentation of ELISA.

(*b*) Give the comparative advantages and disadvantages of HPLC.

(*c*) Write the factors affecting fluorescence.

(*d*) Discuss the importance and advantages of Radioimmunoassay in pharmaceutical analysis.

(*e*) What are the factors influencing vibrational frequencies ?

(*f*) Discuss the various rules which are helpful in predicting peak in the mass spectrum.

(*g*) Write about instrumentation of UV-visible spectroscopy.

(*h*) Describe different interference observed in Atomic absorption spectroscopy.

(*i*) Write a short note on different types of columns used in HPLC.

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

QT—12—2023

FACULTY OF SCIENCE AND TECHNOLOGY

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

NOVEMBER/DECEMBER, 2023

QUALITY MANAGEMENT SYSTEM

MQA-102T

(Thursday, 28-12-2023) **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*) Define out of trend (OOT).

(*b*) What is quality ? Enlist *four* characters of quality.

(*c*) What is cost of external failure ?

(*d*) Write quality policy for ideal organization.

(*e*) Give the elements of TQM.

(*f*) What is IPQC ?

(*g*) Give the applications of statistical process control in health environment.

(*h*) Define customer and vendor.

(*i*) What are control charts ? Enlist types of control charts.

(*j*) Write ideal aspects to establish vision and mission of an organization.

P.T.O.

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

(*a*) Discuss in detail process involved in vendor qualification, annual product review and batch release.

(*b*) Discuss in detail benchmarking process with its advantages.

(*c*) Discuss ICH Q10 guidelines.

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

(*a*) Discuss quality by design process.

(*b*) Discuss six system inspection model.

(*c*) Describe various techniques used under TQM.

(*d*) Write the features of quality management review. Discuss procedural guidelines for NABL certification.

(*e*) Explain Mekinsey 7s model.

(*f*) Discuss ICH guidelines for stability testing of drug substances.

(*g*) Define statistical process control. Discuss process control measurement and quality impovement in an industry.

(*h*) What is cost of quality ? Explain various factors affecting cost of quality.

(*i*) Discuss CFR-21 part 11 in detail.

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

QT—22—2023

FACULTY OF SCIENCE AND TECHNOLOGY

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

NOVEMBER/DECEMBER, 2023

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA102T

(Quality Control and Quality Assurance)

(Saturday, 30-12-2023) **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.

(*iii*) Answer to the point only.

1. Solve the following : 10×2=20

(*a*) How to calculate expiry date ?

(*b*) Give the importance of distribution records.

(*c*) What is Quality ?

(*d*) Enlist ICH quality guidelines.

(*e*) What is process deviation ?

(*f*) What is drug master file ?

(*g*) Enlist quality control test parameters for capsules.

P.T.O.

(*h*) What is change control ?

(*i*) Define quality control and quality assurance.

(*j*) What is trademark ?

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

(*a*) Explain schedule M requirements related to premises, sanitation and hygiene.

(*b*) What is GLP ? Describe various features of GLP.

(*c*) Discuss various modules of eCTD documents.

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

(*a*) Explain steps involved in equipment qualification.

(*b*) What is IPR ? Explain its types.

(*c*) Explain various quality control tests for container, closures and secondary packaging material.

(*d*) What is quality audit ? Explain the process in detail.

(*e*) Give a detailed account on stability testing of dosage form as per ICH guideline.

(*f*) Write importance of documentation. Elaborate MFR and BMR.

(*g*) Explain good warehousing practices in pharmaceuticals.

(*h*) What is SOP ? Explain the various SOPs in manufacturing area.

(*i*) Explain various components of quality assurance.

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

QT—32—2023

FACULTY OF SCIENCE AND TECHNOLOGY

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

JANUARY, 2024

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

Paper-MQA-103T

(Tuesday, 2-1-2024) **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 the following questions : 10×2=20

(*a*) What is meant by SUPAC ?

(*b*) What are the different goals of Preformulation studies ?

(*c*) Why to conduct Pilot Plant scale up. Give reason ?

(*d*) Why is plastic not suitable material for packaging. Give reason.

(*e*) What is the role of technology transfer in pharmaceutical industry.

(*f*) Differentiate between IND and NDA.

(*g*) What is the role of Surfactant in solubilization ?

(*h*) Why to carry out process evaluation in pilot plant scale up ?

(*i*) Give ideal requirements of Packaging Materials.

(*j*) What are the objectives of technology transfer in Pharmaceutical Industry ?

P.T.O

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

(*a*) Explain in brief drug discovery and development process.

(*b*) What is preformulation ? Explain methods to study crystal properties.

(*c*) Write notes on :

(*i*) Technology Transfer Plan

(*ii*) Factors influencing technology transfer.

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

(*a*) Describe clinical research process in detail.

(*b*) What is Polymorphism ? Explain its significance in preformulation study.

(*c*) Draw and explain well labelled layout of Tablet pilot plant.

(*d*) Describe in short different types of pharmaceutical packaging materials.

(*e*) Describe qualitative and quantitative technology models.

(*f*) Discuss quality control test for containers and closures.

(*g*) What are the different opportunities and challenges of new era of drug product ?

(*h*) What is Aseptic Packaging System ? What are advantages and types of aseptic packaging systems ?

(*i*) Explain large scale manufacturing technique of liquid dosage form.

This question paper contains 2 printed pages]

HQ—01—2022

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

MARCH/APRIL, 2023

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Paper-MQA-101-T

(Thursday, 16-03-2023) **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.

(*iii*) Answer to the point only.

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

(*a*) What is process of Deshielding ?

(*b*) Write reason for use of buffer in paper electrophoresis.

(*c*) Enlist different analytical techniques used for isomer determination.

(*d*) Write principle of column chromatography.

(*e*) What is quantum number ?

(*f*) State Bragg's law.

(*g*) Differentiate between stationary phase of HPTLC and TLC.

(*h*) Define with example metastable ion.

(*i*) Write effect of solvent on UV-visible spectrum.

(*j*) Define Quinchers with suitable examples.

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

(*a*) Explain various types of ionization techniques used in MS.

(*b*) Write in detail about instrumentation of NMR.

(*c*) What are different types of molecular vibrations ? Explain factors affecting vibrational frequencies. Support your answer with suitable examples.

P.T.O.

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

(*a*) Write a short note on simultaneous estimation method.

(*b*) Write about Mass fragmentation rule.

(*c*) Write the procedure for ion-exchange chromatography.

(*d*) Write about bonding and antibonding in UV-visible spectroscopy.

(*e*) Give the components of FTIR.

(*f*) Write instrumentation of ELISA.

(*g*) Enlist different columns used in GC with a suitable example.

(*h*) Discuss importance and advantages of RIA.

(*i*) What is chemical shift ? Describe factors affecting chemical shift.

This question paper contains 2 printed pages]

HQ—12—2022

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

MARCH/APRIL, 2023

QUALITY MANAGEMENT SYSTEM

(MQA-102T)

(Saturday, 18-3-2023) **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 the following : 10×2=20

(*a*) What is TQM ?

(*b*) Write different tools used in Quality Risk Management.

(*c*) What is internal and external customer ?

(*d*) Enlist various dimensions of quality.

(*e*) Define out of specification (OOS).

(*f*) What is cost of internal failure ?

(*g*) What are basic requirements for development of quality culture ?

(*h*) Give the significance of ISO 9001 : 2008.

(*i*) Give the advantages of QbD approaches.

(*j*) What is OHSAS 18001 : 2007 ?

P.T.O.

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

(*a*) What is IPQC ? Discuss six system inspection model in detail.

(*b*) Discuss McKinsey 7s model in industry.

(*c*) Discuss NABL certification and accreditation process.

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

(*a*) Describe various tools and techniques used to mitigate risks in pharmaceuticals.

(*b*) Discuss in detail process of area clearance and line clearance.

(*c*) Define and classify customer. Explain procedures for handling customer complaints.

(*d*) Explain various benchmarking attributes in detail.

(*e*) Discuss steps involved in life-cycle management approach.

(*f*) Discuss statistical process control techniques.

(*g*) Discuss OHSAS guidelines for employees.

(*h*) Define Vendor. Discuss qualification of a vendor.

(*i*) Explain various techniques used for quality measurements in manufacturing.

This question paper contains 2 printed pages]

HQ—22—2022

FACULTY OF SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2023

PHARMACEUTICAL QUALITY ASSURANCE

Paper-MQA-102-T

(Quality Control and Quality Assurance)

(Tuesday, 21-03-2023) **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.

(*iii*) Answer to the point only.

1. Answer the following : 10×2=20

(*a*) Define role of institutional animal ethical committee.

(*b*) What are various Sop's for control on animal house ?

(*c*) Enlist quality control test parameters for cream.

(*d*) What is quality culture ?

(*e*) Give the importance of IPR.

(*f*) What is deviation ?

(*g*) Define GMP and GCP.

(*h*) What is mix-up ?

(*i*) Give composition of IAEC.

(*j*) What are the main objectives of ICH ?

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

(*a*) Give importance of documentation. Explain MFR and BMR.

(*b*) What is quality audit ? Explain the quality audit procedure in pharmaceutical industry.

(*c*) What is GLP ? Describe various features of GLP in non-clinical laboratory.

P.T.O.

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

(*a*) How to avoid mix-ups and cross contamination ?

(*b*) Explain various quality control tests for container, closures and secondary packaging material.

(*c*) Write in detail about important points to be covered in preparing SOP in manufacturing premises.

(*d*) Discuss the points to be considered for IPQC in manufacturing & packaging operations.

(*e*) Explain copyright and trademarks.

(*f*) Discuss various components of drug master file.

(*g*) Explain with appropriate examples the role of quality control and quality assurance in pharmaceutical industry.

(*h*) Explain various documentation involved in quality control area.

(*i*) Discuss role, objective and composition of CPCSEA guidelines.

This question paper contains 2 printed pages]

HQ—32—2022

FACULTY OF SCIENCE & TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

MARCH/APRIL, 2023

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

(Friday, 24-03-2023) **Time : 2.00 p.m. to 5.00 p.m.**

Time—Three Hours *Maximum Marks—75*

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

(*ii*) Answer to the point only

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

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

(*i*) What is meant by Nanomorph ?

(*ii*) What is Clinical Research Study ?

(*iii*) Enlist quality control test parameters for containers.

(*iv*) What is role of surfactant in drug product development ?

(*v*) Why is preformulation study important ?

(*vi*) What are ideal qualities of primary containers ?

(*vii*) Define optimization batches.

(*viii*) What is meant by IND ?

(*ix*) Define enteral packaging.

(*x*) What is organoleptic properties ?

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

(*i*) Explain in detail methods to improve solubility of Drugs.

(*ii*) Describe large scale manufacturing techniques of parenteral dosage forms.

P.T.O.

(*iii*) Write notes on :

(*a*) Product registration guidelines under CDSCO

(*b*) Closure of pharmaceutical containers.

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

(*i*) Explain medical device packaging.

(*ii*) Discuss stability testing during drug product development.

(*iii*) Enumerate various techniques for study of crystal properties of drug.

(*iv*) Draw and explain well labelled layout of Tablet pilot plant.

(*v*) Describe in short different types of Pharmaceutical Packaging materials.

(*vi*) What are the different opportunities and challenges of new era of drug product ?

(*vii*) What is Aseptic Packaging System ? What are the advantages and types of aseptic packaging systems ?

(*viii*) Write in short about Abbreviated New Drug Application.

(*ix*) Discuss the issues facing modern drug packaging.

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

CN—01—2019

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

OCTOBER/NOVEMBER, 2019

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPA-101T)

(Wednesday, 27-11-2019) **Time : 10.00 a.m. to 1.00 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*) Define quenching with suitable examples.

(*b*) Write the name of the solvzent used in NMR.

(*c*) Write the factors which affect on resolution in HPLC.

(*d*) How many modes of vibrations present into chloroform ?

(*e*) Write on molecular ion peak.

(*f*) Write about ion exchange chromatography.

(*g*) What is process of shielding ?

(*h*) What are the basic components of XRD ?

(*i*) Mention various detectors used in GC.

(*j*) Write the principle of affinity chromatography.

(*k*) What is the difference between HPLC and UHPLC.

(*l*) What are the differences between single focusing and double facusing mass spectrometer ?

P.T.O.

2. Answer any *two* : 2×10=20

(*a*) Classify chromatographic methods based on mechanism of separation and add a note on HPTLC chromatography.

(*b*) Explain the theory of Mass spectroscopy and add a note on matrix assisted laser desorption ionization mass spectroscopy.

(*c*) Explain the various components and working principle of fluorescence and phosphorescence spectrophotometer.

3. Answer any *seven* : 7×4=28

(*a*) Discuss about spin-spin coupling and coupling constant.

(*b*) Describe working of flame ionisation detector and thermal conductivity detector.

(*c*) Write on principle, instrumentation and p'ceutical applications of DTA.

(*d*) Explain the principle and write the applications of potentiometry.

(*e*) Explain how the calibration techniques are adopted in GC.

(*f*) Explain moving boundary electrophorens–principle and application.

(*g*) Discuss in detail about the principle and instrumentation of HPLC.

(*h*) Describe the various sampling techniques in IR.

(*i*) Predict the splitting pattern for ethanol in 'HNMR.

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

CN—06—2019

FACULTY OF SCIENCE AND TECHNOLOGY

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

OCTOBER/NOVEMBER, 2019

QUALITY MANAGEMENT SYSTEM

(MQA-102T)

(Friday, 29-11-2019) **Time : 10.00 a.m. to 1.00 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. Answer any *ten* of the following : 10×2=20

(*a*) Enlist the various dimensions of quality.

(*b*) Give the significance of benchmarking.

(*c*) Define out of specification (OOS).

(*d*) Enlist the various components of Total Quality Management.

(*e*) What is customer ? What do you mean by customer focus ?

(*f*) Enlist various tools and techniques used for quality risk management.

(*g*) Give the importance of statistical process control.

(*h*) Give the basic criteria for selection of a vendor.

(*i*) What do you understand about cost of internal failure.

(*j*) Give the advantages of quality by design (QbD) approaches.

(*k*) What are control charts ? Enlist the types of control charts.

(*l*) Give the significance of ISO 9001 : 2008.

P.T.O.

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

(*a*) Discuss Mckinsey 7s model in industry.

(*b*) Discuss in detail NABL certification and accreditation process.

(*c*) Discuss in detail ICH Q9 guidelines for quality risk management.

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

(*a*) What are customer complaints ? Discuss handling of customer complaints in detail.

(*b*) Explain various models of cost of quality.

(*c*) Discuss OSHAS guidelines for employees.

(*d*) Explain six system inspection model related to production system and equipment system.

(*e*) Describe various stages involved in product returns and recalls.

(*f*) What is QbD approach ? Explain various components in detail.

(*g*) Describe various tools and techniques used to mitigate risks in pharmaceuticals.

(*h*) Explain various types of benchmarking.

(*i*) Explain various approaches used for measuring process control and quality improvement of pharmaceuticals.

This question paper contains 2 printed pages]

CN—12—2019

FACULTY OF SCIENCE AND TECHNOLOGY

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

OCTOBER/NOVEMBER, 2019

(PCI Pattern)

PHARMACEUTICAL QUALITY ASSURANCE

Paper (MQA103T)

(Quality Control and Quality Assurance)

(Monday, 2-12-2019) **Time : 10.00 a.m. to 1.00 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*) Enlist the various SOP's in animal house.

(*b*) Give the importance of IPR.

(*c*) What is quality culture ?

(*d*) Enlist quality control test parameters for ointment and creams.

(*e*) What is salvaging ?

(*f*) What are main objectives of ICH ?

(*g*) What is change control ?

(*h*) Differentiate between quality control and quality assurance.

(*i*) Give the importance of record keeping in Q.C. area.

(*j*) Give the importance of waste management.

(*k*) What is cross contamination ?

(*l*) Enlist ICH quality guidelines.

P.T.O.

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

(*a*) Discuss ICH Q_1A (R_2) guidelines.

(*b*) What is GCP ? Discuss various features of GCP.

(*c*) Explain various documentation involved in pharmaceutical industry.

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

(*a*) Explain with appropriate examples the role of quality control in pharma industry.

(*b*) Discuss role, objective and composition of CPCSEA guideline.

(*c*) What is quality audit ? Explain regulatory audit process.

(*d*) Discuss various points to be considered for IPQC in manufacturing operations.

(*e*) Explain sanitation and premises as per schedule M.

(*f*) Write importance of documentation. Elaborate MFR and BMR.

(*g*) Explain ECTD modules as per ICH guidelines.

(*h*) Discuss role of quality assurance in pharmaceutical industry.

(*i*) Explain concept of change control and deviation in pharma industry.

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

CN—18—2019

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

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

NOVEMBER/DECEMBER, 2019

PHARMACEUTICAL QUALITY ASSURANCE

Paper (MQA-104 T)

(Product Development and Technology Transfer)

(Wednesday, 4-12-2019) **Time : 10.00 a.m. to 1.00 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* questions : 10×=20

(*a*) What is NDA ?

(*b*) What is co-solvency ? Give its significance.

(*c*) Write about post-marketing surveillance.

(*d*) Define pharmaceutical packaging. Enlist different packaging materials.

(*e*) Define Technology Transfer in Pharmaceuticals.

(*f*) What is Aseptic Packaging ?

(*g*) Write about Technology Transfer Plan.

(*h*) Give significance of pilot plant scale up.

(*i*) Define polymorphism. Give its importance.

(*j*) What is large scale manufacturing technique ?

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

(*a*) Describe in detail about ANDA.

(*b*) Explain stability testing during product development.

(*c*) Write in detail large scale manufacturing technique for Parenteral dosage forms.

P.T.O.

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

(*a*) Write about selection and evaluation of pharmaceutical packaging material.

(*b*) Describe various qualitative and quantitative technology models for technology transfer.

(*c*) Discuss the quality control tests for closures and secondary packaging material.

(*d*) Discuss on development report in pharmaceutical R and D.

(*e*) Write about SNDA.

(*f*) Describe various methods to improve solubility of drugs.

(*g*) Discuss on design and layout of pilot scale up study.

(*h*) What are the requirements of Pharmaceutical Packaging ? Write about medical device packaging.

(*i*) Write about product registration guidelines of USFDA.

This question paper contains 2 printed pages]

CM—1—2019

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

MARCH/APRIL, 2019

MODERN PHARMACEUTICAL ANALYSIS TECHNIQUES

(MPA-101-T)

(Monday, 22-4-2019) **Time : 10.00 a.m. to 1.00 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*) What is nitrogen rule ?

(*b*) Give the limitation of XRD.

(*c*) What is shielding and deshielding ?

(*d*) Give the principle of affinity chromatography.

(*e*) What is the difference in operation principle of AAS and AES ?

(*f*) Write different types of columns used in HPLC.

(*g*) Write the name of factors affect on migration of DNA in electrophoresis.

(*h*) What are chromophores and auxochromes ?

(*i*) Calculate numebr of vibrations presnt in methanol.

(*j*) Write the block diagram of gas chromatography.

(*k*) Give the advantages of HPTLC over other techniques.

(*l*) Give the advantage of MALDI.

P.T.O.

2. Solve any *two* : 10×2=20

(*a*) Give the principle of XRD. Write the essential part of differactometer. Discuss in detail instrumentation of it.

(*b*) Give the principle and FT-NMR and ^{13}C NMR. Explain spin-spin coupling and coupling constant in detail.

(*c*) Give the different types of mass spectroscoy. Discuss APPI analyzers of quadruple and time of flight.

3. Solve any *seven* : 7×5=35

(*a*) Discuss derivative UV-vis spectroscopy in Analytical Chemistry.

(*b*) Explain different types of ion produced in mass spectroscopy.

(*c*) Explain various application and strength of XRD.

(*d*) Discuss various types of column used in HPLC.

(*e*) Explain various factors affecting vibrational frequencies and give application of IR spectroscopy.

(*f*) Discuss various steps involved during HPTLC.

(*g*) What is chemical shift ? Explain factors influencing chemical shift.

(*h*) What are quenchers ? Explain various types and quenchers.

(*i*) Explain isolation technique in ion exchange chromatography. Discuss various factors affecting resolution through it.

This question paper contains 2 printed pages]

CM—6—2019

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

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

MARCH/APRIL, 2019

QUALITY MANAGEMENT SYSTEM

Paper PQA-101T

(Wednesday, 24-4-2019) **Time : 10.00 a.m. to 1.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

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

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

1. Solve any *ten* : 10×2=20

(*a*) Write principle of TQM and enlist main component of it.

(*b*) What is meant by customer delight ?

(*c*) Give the significance of quality matrix.

(*d*) Write the various objectives of statistical approaches used for quality sustenance.

(*e*) Write in short cost of quality.

(*f*) What is vendor qualification ?

(*g*) Write about risk management tools.

(*h*) Give the advantages of statistical control.

(*i*) What is concept of IPQC.

(*j*) Give the important benefits of implementation of QbD approaches.

(*k*) Define SPC. Write the inherent capability from control chart analysis.

(*l*) Give the principle of six sigma.

2. Solve any *two* : 2×10=20

(*a*) Discuss various approaches used in risk assessment, controls review and various tools used as per ICH guideline ICH Q9.

P.T.O.

(*b*) Explain the secrets and steps towards establishing a successful quality circle program in a firm.

(*c*) Discuss quality by design and process development in pharmaceuticals.

3. Solve any *seven* : 7×5=35

(*a*) Discuss McKinsey 7S model in detail.

(*b*) Describe various dimensions of quality.

(*c*) Describe returns and recalls in pharmaceutical industry.

(*d*) State and explain various barriers to TQM implementation in an organization.

(*e*) What is quality culture ? Explain various approaches to maintain quality culture.

(*f*) Discuss the ICH Q10 guideline of pharmaceutical quality management.

(*g*) Explain packing and labelling system in six system inspection model.

(*h*) Explain various factors affecting on customers perceptions.

(*i*) Discuss corrective and preventive action in Industry.

This question paper contains 2 printed pages]

CM—12—2019

FACULTY OF SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2019

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA-102T

(Quality Control and Quality Assurance)

(Friday, 26-4-2019) **Time : 10.00 a.m. to 1.00 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*) Differentiate between quality control and quality assurance.

(*b*) Enlist various SOP's for control on animal house.

(*c*) What is quality culture ?

(*d*) What are in-process quality control test for tablets ?

(*e*) What is trade mark ?

(*f*) Define mix up and cross contamination.

(*g*) What is expiry date ?

(*h*) Give the minimum qualification required for IAEC member.

(*i*) What are the functions of quality control department ?

(*j*) Enlist quality control test parameters for ointments and creams.

(*k*) What is good warehousing practice ?

(*l*) What is salvaging ?

P.T.O.

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

(*a*) What is GMP ? Explain schedule M in detail.

(*b*) Discuss ICH Q1A (R_2) guideline.

(*c*) Enlist and explain the SOP's for control on animal house.

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

(*a*) Discuss role of QA in pharmaceutical industry.

(*b*) Explain raw material in process and finished products specifications.

(*c*) What is DMF ? Explain its types.

(*d*) Explain importance of intellectual property rights.

(*e*) Discuss various methods to avoid mix ups and cross contamination.

(*f*) Write importance of documentation. Elaborate MFR and BMR.

(*g*) What is quality audit ? Explain the process in detail.

(*h*) Explain handling of scrap and waste disposal.

(*i*) Discuss the measures to be taken while handling electronic data.

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

CM—18—2019

FACULTY OF SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2019

(New Course)

PHARMACEUTICAL QUALITY ASSURANCE

(MQA-103T)

(Product Development and Technology Transfer)

(Monday, 29-4-2019) **Time : 10.00 a.m. to 1.00 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 post-marketing surveillance ?

(*b*) What is technology transfer ?

(*c*) Enlist quality control test parameters for container.

(*d*) What is clinical research study ?

(*e*) What is complextion ?

(*f*) Enlist physical modification techniques for solubility enhancement.

(*g*) Give importance of cosolvency.

(*h*) What is development report ?

(*i*) Enlist quality control test parameters for solids.

(*j*) What is stability study ?

(*k*) Define optimization batch.

(*l*) What is impurity profiling.

P.T.O.

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

(*a*) Explain pilot plant scale up study in pharmaceutical industry.

(*b*) Describe various methods to improve solubility of drug substance.

(*c*) Discuss product registration guideline of CDSCO.

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

(*a*) Explain in detail clinical trials in drug discovery.

(*b*) Describe the factors influencing technology transfer.

(*c*) Explain various methods used in manufacturing of oral liquids.

(*d*) Explain stability testing during product development.

(*e*) Describe medical device packaging with its quality control tests.

(*f*) Explain various problems during technology transfer from R&D to production.

(*g*) Explain various dosage forms and their packaging requirements.

(*h*) Discuss various techniques for the study of crystal properties and polymorphism.

(*i*) Explain qualitative and quantitative technology models.

This question paper contains 2 printed pages]

CI—1—2018

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharmacy (First Semester) EXAMINATION

NOVEMBER/DECEMBER, 2018

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Paper MPA-101-T

(Monday, 3-12-2018) **Time : 10.00 a.m. to 1.00 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 the questions wherever necessary.

1. Solve **10** out of 12 : 2×10=20

(*a*) What is effect of sample thickness on the absorption of X-rays ?

(*b*) Write ideal characteristics of ion exchange resin.

(*c*) Give the nitrogen rule.

(*d*) Define quenching with suitable examples.

(*e*) Calculate number of mode of vibrations present into CCl_4.

(*f*) Write the name of solvent used in NMR.

(*g*) What is isotopic peak ? Give its significance.

(*h*) Write the principle of affinity chromatography.

(*i*) What is gel electrophoresis ?

(*j*) What is McLafferty rearrangement ?

(*k*) Why derivatisation is needed in gas chromatography ?

(*l*) Write the factors which affect on resolution in HPLC.

P.T.O.

2. Solve *two* out of three :

(*a*) Explain number of ions produced in mass spectrum. Discuss FAB and MALDI technique in detail.

(*b*) What is shielding and deshielding effect in NMR ? Discuss various factors influencing chemical shift.

(*c*) Enlist various vibrations in molecules. Describe various interpretation rules for IR spectrum.

3. Solve *seven* out of nine : 5×7=35

(*a*) Give the various types of mass spectroscopy. Discuss ESI techniques for determination of mass.

(*b*) Explain theory and laws associated with UV spectroscopy.

(*c*) Describe in detail sampling techniques in IR spectroscopy.

(*d*) Explain various factors affecting on fluorescence.

(*e*) Give the theory of AAS. Discuss instrumentation of it.

(*f*) Discuss principle and factor affecting resolution of paper chromatography.

(*g*) What is Bragg's law ? Write the types of crystal affecting X-ray differaction result.

(*h*) Discuss various detectors used in Gas chromatography.

(*i*) Give the comparative explanation on HPLC and UHPLC.

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CI—6—2018

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

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

NOVEMBER/DECEMBER, 2018

QUALITY MANAGEMENT SYSTEM

(MQA-101-T)

(Wednesday, 5-12-2018) **Time : 10.00 a.m. to 1.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

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

(*ii*) Draw neat diagram wherever necessary.

(*iii*) Answer the questions to the point.

1. Solve *ten* out of twelve : 10×2=20

(*a*) Write ideal aspects to establish vision and mission of organization.

(*b*) Give the main component of TQM.

(*c*) What is OOS ?

(*d*) Give the benefits of Benchmarking.

(*e*) What is meant by internal and external customer ?

(*f*) Give the application of statistical process control in health care improvement.

(*g*) Give the important features of ICH Q9.

(*h*) Give the objective of life cycle management approaches.

(*i*) What are basic requirements for development of quality culture ?

(*j*) Give the importance of knowledge management.

(*k*) Give the ICH guideline for stability testing of drug prdouct (Name the guideline)

(*l*) What is HACCP ?

P.T.O.

2. Solve *two* out of three : 2×10=20

(*a*) What is quality matrix ? Describe the WHO GLP requirement and CFR-21 part 11.

(*b*) Write the features of operational excellence. Describe statistical process control techniques.

(*c*) What is concept of IPQC ? Discuss *six* system inspection models in detail.

3. Solve *seven* out of nine : 7×5=35

(*a*) Classify different kinds of customer ? Explain procedures handling customer complaints.

(*b*) Discuss various models used in cost of quality.

(*c*) Discuss various types of benchmarking and explain approaches used to implement it.

(*d*) Describe in detail process of area clearance and line clearance.

(*e*) Explain various techniques used for quality measurement in manufacturing.

(*f*) Write the benefits of process analytical technology used for process development. Enlist various tools used in it.

(*g*) Write benefits of QBD. Explain key area considered for process development.

(*h*) What different models can be studied to develop strategic decision under competitive analysis ?

(*i*) Explain in detail optimising costs for ointment manufacturing unit.

This question paper contains 2 printed pages]

CI—12—2018

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

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

NOVEMBER/DECEMBER, 2018

PHARMACEUTICAL QUALITY ASSURANCE

(MQA-120T)

(Quality Control and Quality Assurance)

(Saturday, 8-12-2018) **Time : 10.00 a.m. to 1.00 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*) Enlist the objectives of ICH.

(*b*) What is GMP ?

(*c*) What is quality ?

(*d*) Enlist the quality control parameters for capsules.

(*e*) What is process deviation ?

(*f*) What is change control ?

(*g*) What are the key elements for retention of records ?

(*h*) Explain importance of purchase specification.

(*i*) What is quality culture ?

(*j*) Define job responsibilities of personnel in QA department.

(*k*) How to calculate expiry date ?

(*l*) What is IPR ?

P.T.O.

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

(*a*) Explain IPQL in manufacturing and packaging operations.

(*b*) What is GLP ? Describe various features of GLP.

(*c*) What is quality audit ? Explain the process in detail.

3. Solve any *seven* : 7×5=35

(*a*) Describe various functions of quality control and quality assurance department.

(*b*) How to avoid cross contamination and mix-ups in pharmaceutical industry ?

(*c*) Give the importance of documentation. Elaborate MFR and BMR.

(*d*) Explain quality control tests for container, closure and secondary packaging.

(*e*) Explain good warehousing practices in pharamaceuticals.

(*f*) What are various SOPs for control on animal house ?

(*g*) Discuss the importance of inprocess quality control tests in pharma industry.

(*h*) Explain precautionary measures taken for control on electronic data.

(*i*) Explain sanitation procedure of manufacturing premises.

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CI—18—2018

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

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

NOVEMBER/DECEMBER, 2018

(PCI Syllabus)

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA-103T

(Product Development and Technology Transfer)

(Tuesday, 11-12-2018) **Time : 10.00 a.m. to 1.00 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 NDA ?

(*b*) Enlist the special equipments used in liquid dosage form.

(*c*) Enlist the quality control test parameters for secondary packaging material.

(*d*) Define technology transfer in pharmaceuticals.

(*e*) What is clinical research process ?

(*f*) What is impurity profile of drug ?

(*g*) Give importance of co-solvency in new product development.

(*h*) Give significance of pilot plant scale up techniques.

(*i*) Enumerate factors influencing technology transfer.

(*j*) Enlist the quality control test parameters for solid dosage form.

(*k*) What is Aseptic packaging system ?

(*l*) Enlist pharmaceutical dosage form packaging requirements.

P.T.O.

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

(*a*) Explain the various problems during technology transfer from R&D to production.

(*b*) Describe ANDA in detail.

(*c*) Describe methods to improve solubility of drug substance.

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

(*a*) Discuss product registration guidelines of USFDA.

(*b*) Describe various methods used in manufacturing of liquid dosage form.

(*c*) Give the opportunities and challenges in new drug product development.

(*d*) Define external packaging with its quality control tests.

(*e*) Explain development report in technology transfer.

(*f*) Explain concept and design of pilot plant scale up study.

(*g*) Describe post-marketing surveillance of a new drug.

(*h*) Explain stability testing during product development.

(*i*) Explain preformulation protocol.

This question paper contains 2 printed pages]

DF—1—2018

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

MARCH/APRIL, 2018

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Paper MPA-101-T

(Friday, 20-4-2018) **Time : 10.00 a.m. to 1.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

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

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

1. Solve *ten* out of twelve : 10×2=20

(*a*) What are the basic components of XRD ?

(*b*) Give the principle of ion-exchange chromatography.

(*c*) What is Isotopic peak ? Give its significance.

(*d*) Write the variables influencing absorption of UV radiation.

(*e*) Calculate number of mode of vibrations present into methanol molecule.

(*f*) What is the difference between ^{13}C-NMR and 1H-NMR ?

(*g*) Enlist the materials used in gel electrophoresis.

(*h*) Mention various detectors used in GC.

(*i*) Give the principle of AAS.

(*j*) Write the significance of affinity chromatography.

(*k*) What is McLafferty rearrangement ?

(*l*) Write the principle of affinity chromatography.

2. Solve *two* out of three : 2×10=20

(*a*) What is chemical shift ? Write about splitting of signal. Explain in detail about spin-spin coupling.

P.T.O.

(*b*) Give the various types of mass spectroscopy. Discuss FAB and MALDI technique for determination of mass.

(*c*) Write significant role of UV, IR, NMR and MS in structural elucidation with suitable example.

3. Solve *seven* out of nine : 7×5=35

(*a*) Enlist and explain electronic transition in UV.

(*b*) Explain different types of column in HPLC.

(*c*) Discuss instrumentation of column chromatography.

(*d*) What is Bragg's equation ? Write its importance in X-ray.

(*e*) What is FTIR ? Enlist important advantage of it.

(*f*) Define with examples spin-spin coupling and J costant.

(*g*) Write in brief about working of qudrapole analyzer.

(*h*) Give comparative advantages and disadvantage of HPLC and GC.

(*i*) Instrumentation of double beam UV-visible spectroscopy.

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DF—06—2018

FACULTY OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

M. Pharm. (First Semester) EXAMINATION

MARCH/APRIL, 2018

QUALITY MANAGEMENT SYSTEM

(MQA-101T)

(Monday, 21-4-2018) **Time : 10.00 a.m. to 1.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

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

(*ii*) Draw neat diagrams wherever necessary.

(*iii*) Answer the questions to the point.

1. Solve 10 out of 12 : 10×2=20

(*a*) Write quality policy for ideal organization.

(*b*) What is OHSAS 18001 : 2007 ?

(*c*) What is OOT ?

(*d*) Give the significance of benchmarking.

(*e*) What are the ideal requirement of customer ?

(*f*) Give the elements of TQM.

(*g*) Write different tools used in quality risk management.

(*h*) What are the objectives of life-cycle management approach.

(*i*) What is CAPA ?

(*j*) Give the importance of knowledge management.

(*k*) What are basic requirements for quality culture ?

(*l*) Write ICH guidlines related to PAT implementation.

P.T.O.

2. Solve *two* out of three : 20

(*a*) Discuss in detail implementation of OHSAS 18001 implemention model planning for hazard identification, risk assessment and risk control.

(*b*) What is concept of IPQC ? Discuss six system inspection model in detail.

(*c*) Give the features of process capability. Discuss various aspects of estimating inherent or potential capability from control chart analysis.

3. Solve any *seven* out of nine : 7×5=35

(*a*) What are customer perceptions of quality ? Explain term customer satisfaction and customer delisht.

(*b*) What is cost of quality ? Explain various factors affecting on it.

(*c*) Explain various benchmarking attributes in detail.

(*d*) Discuss systematic process involved in product returns and recalls.

(*e*) What is Kaizen ? Explain various toos used for quality improvement.

(*f*) Discuss various tools and techniques used for process understanding.

(*g*) Write objectives of QBD. Explain opportunity area for process development.

(*h*) Explain in detail optimising costs for pharmaceutical products.

(*i*) What are different models used to study competitive analysis for strategic decision in industry.

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DF—12—2018

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2018

PHARMACEUTICAL QUALITY ASSURANCE

Paper (MOA-102T)

(Quality Control and Quality Assurance)

(Wednesday, 25-4-2018) **Time : 10.00 a.m. to 1.00 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*) What is quality ?

(*b*) Enlist the objectives of ICH.

(*c*) Give the importance of training in pharmaceutical industry.

(*d*) Enlist the quality control parameters for tablet.

(*e*) What is change control ?

(*f*) What are the key elements for retention of records.

(*g*) What is cross contamination ?

(*h*) Enlist the instruments used in animal house.

(*i*) Enlist IPQC test for ointments.

(*j*) Define job responsibilities personnel in QA department.

(*k*) How to calculate yield in production ?

(*l*) What is IPR ?

P.T.O.

2. Solve any *two* : 2×10=20

(*a*) What is GLP ? Describe the various features of GLP.

(*b*) Explain in detail regularly requirement of pharma facilities with reference to schedule m.

(*c*) What is quality audit ? Explain the process in detail.

3. Solve any *seven* : 7×5=35

(*a*) Describe various functions of quality control and quality assurance a department.

(*b*) Explain quality control tests for container closure and secondary packaging.

(*c*) Discuss the steps involved in equipment qualification.

(*d*) Explain good warehousing practices in pharmaceutical.

(*e*) Explain various components of quality assurance.

(*f*) Discuss importance of in-process quality control tests in pharma industry.

(*g*) Explain precautionary measures taken for control as electronic data.

(*h*) Explain NABL certification process in India.

(*i*) Discuss in detail sanitation procedure of manufacturing premises.

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FB—01—2017

FACULTY OF PHARMACEUTICAL SCIENCE & TECHNOLOGY

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

NOVEMBER/DECEMBER, 2017

MODERN PHARMACEUTICAL ANALYSIS TECHNIQUES

Paper MPA-101T

(Tuesday, 21-11-2017) **Time : 10.00 a.m. to 1.00 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 the questions wherever necessary.

1. Solve 10 out of 12 : 10×2=20

(*a*) What are the important parameters of X-ray diffraction ?

(*b*) Enlist the factors affecting on ion exchange separation.

(*c*) What is metastable ions ?

(*d*) Enlist various electronic transitions by absorption of UV in molecules.

(*e*) Calculate number of mode of vibrations present into ethanol.

(*f*) What is quantum numbers ? Write suitable examples.

(*g*) What are the pros and cons of gel electrophoresis ?

(*h*) Mention various types of column used in HPLC.

(*i*) Write the various detectors used in Gas chromatography.

(*j*) Enlist the material used in gel electrophoresis.

(*k*) Give the principle of AAS.

(*l*) Write principle of column chromatography.

2. Solve *two* out of three : 2×10=20

(*a*) Give the various types of mass spectroscopy. Explain ionization techniques used in it. Write number of ions produced in mass spectroscopy.

P.T.O.

(*b*) What are mode of molecular vibration ? Explain factor affecting vibrational frequencies. Write the applications of IR spectroscopy.

(*c*) Write significant role of UV, IR, NMR and MS in structural elucidation with suitable examples.

3. Solve *seven* out of nine : 7×5=35

(*a*) Discuss instrumentation of spectrofluorimetry.

(*b*) What is Bragg's equation ? Write its importance and challenges of it.

(*c*) Write in brief about working of quadruple analyzer.

(*d*) Give comparative advantages and disadvantages of HPLC and GC.

(*e*) Explain various electrophoresis techniques. Discuss instrumentation of it.

(*f*) Give the interpretation rules of IR spectrum.

(*g*) Explain spin-spin coupling and J constant.

(*h*) Give the principle of chiral chromatography.

(*i*) Instrumentation of UV-visible spectroscopy.

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FB—3—2017

FACULTY OF PHARMACEUTICAL SCIENCES AND TECHNOLOGY

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

OCTOBER/NOVEMBER, 2017

QUALITY MANAGEMENT SYSTEM

Paper MQA-101-T

(Thursday, 23-11-2017) **Time : 10.00 a.m. to 1.00 p.m.**

Time—Three Hours *Maximum Marks*—75

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

(*ii*) Draw neat diagram wherever necessary.

(*iii*) Answer the questions to the point.

1. Solve *ten* out of 12 : 2×10=20

(*a*) Write quality objectives of any ideal organization.

(*b*) Give the benefit of OHSAS 18001 : 2007.

(*c*) What is CAPA ?

(*d*) Give importance of benchmarking.

(*e*) What are objectives of customer focus ?

(*f*) What is statistical process control ?

(*g*) Write the steps involved in QdD approach.

(*h*) Give the objectives of life cycle management approach.

(*i*) What is concept of IPQC.

(*j*) What are elements of Total Quality Management.

(*k*) Enlists factors affecting cost of Quality.

(*l*) What are the objectives to enhance quality ?

P.T.O.

2. Solve *two* out of three : 2×10=20

(*a*) Write the features of quality management review. Discuss procedural guideline for NABL certification and accreditation.

(*b*) Give the characterstics of process capability. Discuss various tools estimating inherent (aspect) capability from a control chart analysis.

(*c*) Describe in detail process involved in vendor qualification, annual product review and batch release.

3. Solve *seven* out of nine : 7×5=35

(*a*) Explain marketing 7S frame work model in Industry.

(*b*) Explain various types of benchmarkging.

(*c*) Describe techniques used under TQM.

(*d*) Write the principle of QbD approach.

(*e*) Enlist steps involved in life cycle managment approach.

(*f*) Explain in detail optimising costs for pharmaceutical products.

(*g*) Describe detail process of urea clearance/line clearance.

(*h*) Discuss statistical process control techniques.

(*i*) Explain process of hazard identification and risk assessment.

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FB—06—2017

FACULTY OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

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

NOVEMBER/DECEMBER, 2017

(PCI Syllabus)

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA-102T

(Quality Control and Quality Assurance)

(Saturday, 25-11-2017) **Time : 10.00 a.m. to 1.00 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*) Enlist ICH quality guidelines.

(*b*) What is GMP ?

(*c*) Enlist the quality control parameters for capsules.

(*d*) Give the importance of distribution record.

(*e*) What is process deviation ?

(*f*) Explain importance of purchase specification.

(*g*) What is mix-ups in pharmaceutical industry ?

(*h*) What is quality culture ?

(*i*) Enlist key elements of raw material analysis.

(*j*) How to calculate expiry date ?

(*k*) Differentiate between quality control and quality assurance.

(*l*) What are precautionary measures to be taken while manufacturing of bulk products ?

P.T.O.

2. Solve any *two* : 2×10=20

(*a*) Explain IPQC in manufacturing and packaging operations.

(*b*) Give a detailed account on stability testing of dosage form as per ICH guideline.

(*c*) What is SOP ? Explain important points to be covered in preparing SOP in manufacturing premises.

3. Solve any *seven* : 7×5=35

(*a*) Explain process of quality audit.

(*b*) Give importance of documentation. Elaborate MFR and BMR.

(*c*) How to avoid cross contamination and mix-ups in pharmaceutical industry ?

(*d*) Discuss ICH guideline of QIA(F_2).

(*e*) What are various SOPs for control in animal house ?

(*f*) Explain significance of GLP in not clinical laboratory testing.

(*g*) Discuss various components of quality control dept.

(*h*) Explain importance of finished products quality control tests in pharmaceuticals.

(*i*) What are the measures to be taken while handling electronic data ?

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FB—09—2017

FACULTY OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

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

NOVEMBER/DECEMBER, 2017

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA-103T

(Product Development and Technology Transfer)

(Monday, 27-11-2017) **Time : 10.00 a.m. to 1.00 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*) What is ANDA ?

(*b*) What is Nanomorph ?

(*c*) Enlist the special equipments used in liquid dosage form.

(*d*) Enlist the quality control test parameters for closures.

(*e*) Define technology transfer in pharmaceuticals.

(*f*) Enumerate factors influencing technology transfer.

(*g*) Define surfactants role in drug product development.

(*h*) What is clinical research study ?

(*i*) Enlist issues facing by modern drug packaging.

(*j*) What is co-solvency ?

(*k*) Give challenges in new era of drug product.

(*l*) Define preformulation with its importance.

2. Solve any *two* : 2×10=20

(*a*) Explain pilot plant scale up study in pharmaceutical industry.

(*b*) Describe various methods to improve solubility of drug substances.

(*c*) Explain the development and information content for IND.

P.T.O.

3. Solve any *seven* : 7×5=35

(*a*) Discuss product registration guidelines of CDSCO.

(*b*) Explain stability testing during product development.

(*c*) Describe various methods used in manufacturing liquid dosage form.

(*d*) Define medical device packaging with its quality control tests.

(*e*) Explain development report in pharmaceutical R and D.

(*f*) Discuss post marketing surveillance of new medicine.

(*g*) Explain the layout of pilot plant of parenteral dosage form.

(*h*) Describe scale up post approval changes in pharmaceutical industry.

(*i*) Explain clinical trails in drug discovery.

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