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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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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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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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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.

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