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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.

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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.

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HQ—22—2022

FACULTY OF SCIENCE AND TECHNOLOGY

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

MARCH/APRIL, 2023

PHARMACEUTICAL QUALITY ASSURANCE

Paper-MQA-103-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.

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HQ—32—2022

FACULTY OF SCIENCE & TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

MARCH/APRIL, 2023

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

(Friday, 24-03-2023) Paper-MQA-104-T **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.