This question paper contains 3 printed pages]

LQ—07—2023

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

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

JULY/AUGUST, 2023

(New Syllabus)

HAZARD AND SAFETY MANAGEMENT

(MQA–201T)

(Tuesday, 11-07-2023) **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. Write the answer of the following : 10×2=20

(*a*) Define fire and explosion.

(*b*) Which tools are used for risk management ?

(*c*) What is an ecosystem ?

(*d*) Which are the combustible gases ?

(*e*) Write the role of decomposers in an ecosystem.

(*f*) How many steps are there in effluent treatment ?

(*g*) Enlist self protective measures against workplace hazards.

P.T.O.

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

(*i*) Write an importance of relief valves.

(*j*) Write the role of scrubbers.

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

(*a*) Discuss the mechanical, electrical and thermal hazards to human. Discuss any *one* types of Hazards in detail.

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

(*c*) What is Preliminary Hazard Analysis ? Describe the critical hazard management system.

3. Answer any *seven* questions : 7×5=35

(*a*) Give the detail about sources and problems associated with mineral resources.

(*b*) Describe renewable resources and its associated problems.

(*c*) Explain structure and function of ecosystems.

(*d*) Write a short note on maintenance of air circulation in sterile and non sterile industries.

(*e*) Explain Industrial hazards and write preventive measures due to fire accident.

(*f*) Mention the sources of chemical hazards and their preventive measures.

(*g*) Explain management of combustible gases and toxic gases.

(*h*) Explain sulphonating hazard and organic solvent hazard in brief.

(*i*) What are the elements of safety programme and explain safety management ?

(*j*) Explain hazards and safety measures due to mechanical and electrical equipments used in Pharma industry.

This question paper contains 2 printed pages]

LQ—17—2023

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharma (Second Semester) EXAMINATION

JULY/AUGUST, 2023

PHARMACEUTICAL QUALITY ASSURANCE

Paper MQA-202T

(Pharmaceutical Validation)

(Thursday, 13-07-2023) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 Hours *Maximum Marks—75*

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

(*ii*) Answer to the point only.

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

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

(*a*) What is validation master plan ?

(*b*) What is operational qualification ?

(*c*) Define treadmarks with examples.

(*d*) What is user requirement specification ?

(*e*) Enlist any *four* ICH quality guidelines.

(*f*) Write ethics in patenting.

(*g*) What is DOP test ?

(*h*) What is vendor certification ?

(*i*) Give applications of HPLC.

(*j*) What is media fill test ?

P.T.O.

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

(*a*) Describe the validation of HVAC system.

(*b*) How to qualify equipments ? What are the steps for the qualification of equipments ?

(*c*) Discuss computer system validation.

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

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

(*b*) Explain the scope and objectives of IPR in pharmacy.

(*c*) Discuss prospective and retrospective process validation.

(*d*) What are contaminants ? How to minimise cross contamination ?

(*e*) Discuss validation parameters involved in granulation and compression of tablet manufacturing.

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

(*g*) Describe qualification of dissolution text apparatus.

(*h*) Discuss various steps in PCT filling.

(*i*) Enlist and explain parameters for analytical method validation as per ICH.

This question paper contains 2 printed pages]

LQ—27—2023

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharma (Second Semester) EXAMINATION

JULY/AUGUST, 2023

PHARMACEUTICAL QUALITY ASSURANCE

MQA 203T

(Audits and Regulatory Compliance)

(Saturday, 15-7-2023) **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 : 10×2=20

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

(*b*) Enlist in process quality control tests for ointment and cream.

(*c*) What is cGMP ?

(*d*) Give advantages of audit.

(*e*) What is Regulatory audit ?

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

(*g*) Differentiate between QA and QC.

(*h*) What is pharmaceutical quality system ?

(*i*) Enlist finished quality measures for packaging materials.

(*j*) What is clean room ?

P.T.O.

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

(*a*) Describe the points to be considered while auditing the HVAC system in detail.

(*b*) How to control raw materials ? Explain vendor audit in detail.

(*c*) What is purified water ? Explain various steps involved in auditing of water for injection system.

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

(*a*) How to perform audit in the bulk pharmaceutical industry ?

(*b*) Explain auditing of quality assurance department.

(*c*) Describe purpose of an Audit in Pharmaceutical Industry.

(*d*) Explain auditing of weighing and warehouse stocks.

(*e*) Discuss planning process of an audit.

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

(*g*) Discuss regulatory requirements for sterile production and packaging.

(*h*) Explain role of ETP in pharmaceuticals.

(*i*) Discuss audit in dry production area.

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LQ—37—2023

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharm (Second Semester) EXAMINATION

JULY/AUGUST, 2023

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Paper MQA 204T

(Tuesday, 18-07-2023) **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 questions : 10×2=20

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

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

(*c*) Distinguish between Hard & Soft gelatin capsule.

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

(*e*) What is QbD ?

(*f*) Write importance of scheduling in plant layout designing.

(g) What is process automation in pharma industry ?

(*h*) Enlist IPQC test for non-sterile solid dosage form.

(*i*) Write advantages and disadvantages of Glass containers.

(*j*) How PAT as a driver for improving quality and reducing cost ?

P.T.O.

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

(*a*) Explain manufacturing flow chart and IPQC test for sterile ointment and suspension.

(*b*) Write in detail about the quality assurance of Glass containers.

(*c*) What is QbD and PAT ? Discuss various elements, tools and concepts in pharmaceutical practices.

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

(*a*) What are the various documents needed to be produced for getting Licence for API or formulation industry ?

(*b*) Write a short note on IPQC for dry powders.

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

(*d*) Describe in short different factors affecting selection of packaging material.

(*e*) Write current approaches and limitations of QbD.

(*f*) Comment on the various factors responsible for the selection of plant location.

(*g*) Explain spheronizers and marumerizers.

(*h*) Comment on Drug-Plastic Interactions.

(*i*) Write a note on advanced sterile product manufacturing technology.