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DF—09—2018

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2018

PHARMACEUTICAL QUALITY ASSURANCE

MQA 2027

(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.

(*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—15—2018

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2018

PHARMACEUTICAL QUALITY ASSURANCE

(MQA-203T)

(Audits and Regulatry Compliance)

(Thursday, 26-4-2018) 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 right indicate full marks.

(*iii*) Answer to the point only.

1. Solve any *ten* 10×2=20

(*a*) Define audit in pharma and classify.

(*b*) What is GMP ?

(*c*) Work function of quality assurance.

(*d*) What is critical system ?

(*e*) What are objectives of audit process ?

(*f*) Which are management responsibilities in audit ?

(*g*) What are different evaluation activities performed in audit ?

(*h*) What do you mean by quality audit ?

(*i*) Write different stages of audit in pharmaceutical.

(*j*) What is quality system approach ?

(*k*) Enlist various regulatry agencies in the world.

(*l*) Differentiate between quality and GMP audit.

P.T.O.-

2. Solve any *two* : 2×10=20

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

(*b*) Describe audit in bulk pharmaceutical industry.

(*c*) Which are different CGMP regulations for pharma industry ?

3. Solve any *seven* : 7×5=35

(*a*) Explain audit in engineering department.

(*b*) Describe audit questionnaire for warehouse department.

(*c*) Explain audit of HVAC system.

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

(*e*) Write about quality assurance maintenance.

(*f*) Explain basic objectives of audit in industry.

(*g*) What is regulatory audit ? Explain types of audits.

(*h*) Write about audit of work for injection system.

(*i*) Write in detail about ve[illegible] for audit.

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DF—21—2018

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2018

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

(MQA-204T)

(Saturday, 28-4-2018) Time : 2.00 p.m. to 5.00 p.m.

Time—3 *Hours* *Maximum Marks*—70

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 : 2×10=20

(*a*) What is QTPP ?

(*b*) How PAT as a driver for improving quality and reducing cost.

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

(*d*) What is OBD ?

(*e*) What is clean in place (CIP) ?

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

(*g*) What are the factors affecting plant layout.

(*h*) Define form fill seal technology (FFS).

(*i*) What is process automation in pharma industry.

(*j*) Enlist ICH stability guidelines.

(*k*) Give applications of fluidized bed technology.

(*l*) Enlist in process quality control test for non-sterile solid dosage forms.

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

(*a*) Explain manufacturing flow chart and IPOC test for sterile emulsion and suspension.

(*b*) Explain in detail functions of process analytical technology based tools and techniques in pharmaceuticals.

(*c*) Describe lyophilization technology in detail.

P.T.O.

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

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

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

(*c*) Discuss role of QA in pharma industry.

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

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

(*f*) Discuss in detail equipments used in a tablet and capsule manufacturing.

(*g*) Explain tools of Process Analytical Technology (PAT) in detail.

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

(*i*) Explain importance of training in pharma industry.

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DF—03—2018

FACULTY OF PHARMACEUTICAL SCIENCES

M. Pharm. (Second Semester) EXAMINATION

MARCH/APRIL, 2018

HAZARDS AND SAFETY MANAGEMENT

(MQA-2014)

(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 FIA ? 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.

2. Solve any *two* of the following : 20

(*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.

3. Solve any *seven* of the following : 35

(*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.