This question paper contains 2 printed pages]

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.

%FLSFDE3068E36A4**3C915%ADEB83B

This question paper contains 2 printed pages]

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 ?

This question paper contains 2 printed pages]

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.