M.Pharm

MPC/MPH/MQA/MPG/MPV/MIP/MPA/MPL-101T

**Roll No.** | | | | | | | | | | |



**Odd Semester Examination, 2019-20**

**M.Pharma (Semester-1)- Pharmaceutical Chemistry**

**(Modern Pharmaceutical Analytical Techniques)**

**Time: 3:00 hrs.** **Max. Marks: 75**

**Total no. of printed pages: 1**

**All questions are compulsory:**

## Section-A

**Q 1. Answer all questions.** **[10x2=20]**

a) Discuss spin-spin coupling

b) Explain principle and detector of IR spectroscopy

c) Define flame emission spectroscopy

d) What is ring rule and Braggs equation.

e) McLafferty rearrangement

f) What is X-ray powder diffraction method.

g) Define Electrophoresis

h) Principle of paper chromatography

i) Define quenching methods in spectrofluorometric analysis

j) Write short note on thin layer chromatography

## Section-B

**Q2. Long Answer type (Attempt any Two):** **[2x10=20]**

a) Explain beer's - Lambert law and write about instrumentation associated with UV.

b) Explain principle instrumentation and application of NMR.

c) Draw well labeled diagram of HPLC and explain principle, detector and application of HPLC.

## Section-C

**Q3. Short Answer Type (Attempt any seven):** **[7x5=35]**

a) Write basic principle and application of potentiometric titration

b) Explain in detail about instrumentation of X-ray crystallography.

c) Discuss nitrogen rule and its applications in mass spectrometry.

d) Write note on coupling constant and chemical shift.

e) Explain principle and application of Gas chromatography

f) Write general rules for predicting prominent peaks in mass spectroscopy.

g) Explain ion exchangers. Discuss about factor affecting ion exchanging separations

h) Explain the principal and application of column chromatography

i) Explain shielding -de shielding effect with one example of each.

j) Explain principle and application of atomic absorption spectrophotometer.

MQA-102(T)

Roll No. | | | | | | | | | | | |



# Odd Semester Examination, 2019-20
## M.PHARMA (SEMESTER-I)
## QUALITY MANAGEMENT SYSTEMS, MQA-102(T)

Time : 3:00 hr | Max. Marks : 75

**Total no. of printed pages: 1**

**Note : Attempt all parts as mentioned :**

**I. ATTEMPT ALL THE QUESTIONS. EACH QUESTION CARRY TWO MARKS. 10x2=20**

Q1. Define statistical process control. List its importance
Q2. Give the stability test storage condition and testing frequency for drug product for accelerated stability studies as per ICH guidelines
Q3. What are the types of cost of quality?
Q4. Define Benchmarking. Classify it.
Q5. Mention the principle and scope of Quality Risk Management
Q6. List various IPQC tests for tablets.
Q7. Write the principles of Quality Management System?
Q8. What are 21 CFR Part 11 requirements?
Q9. What is vendor qualification? What is approved supplier list?
Q10. Define quality. List various dimensions of quality.

**II. ATTEMPT ANY TWO QUESTIONS. EACH QUESTION CARRIES TEN MARKS 2x10=20**

Q1. Elaborate on WHO-GMP requirements for raw materials, quality control system, batch processing records and Master formula records for pharmaceutical products.
Q2. Elaborate on the packaging and labeling system, production system, material system and facility and equipment system w.r.t. system inspection model.
Q3. What is process capability? What is the significance of process capability? Explain the procedure to evaluate it.

**III. ATTEMPT ANY SEVEN QUESTIONS. EACH QUESTION CARRY FIVE MARKS. 7x5=35**

Q1. Give reasons for benchmarking. List the advantages of bench marking
Q2. Write a note on area clearance/line clearance
Q3. Differentiate between OOS and OOT with suitable examples.
Q4. Write a note on NABL certification and accreditation.
Q5. List various components of Drug products as per ICH Q8. Write a short note on any two.
Q6. Write a note on handling customer complaints and understanding customer behavior.
Q7. Write a note on risk assessment.
Q8. What are the aims of ISO 9001:2015. Give brief account of ISO 9001:2015 with respect to performance indicators.
Q9. Write a short note on risk management methodology.

MQA-103(T)

Roll No. | | | | | | | | | | |



# Odd Semester Examination, 2019-20
## M.PHARMA (SEMESTER-I)
## QUALITY CONTROL AND QUALITY ASSURANCE, MQA-103(T)

**Time : 3:00 hr** **Max. Marks : 75**

**Total no. of printed pages: 2**

**Note : Attempt question from all sections as mentioned :**

## Section A

**I. ATTEMPT ALL THE QUESTIONS. EACH QUESTION CARRY TWO MARKS (10X2=20)**

Q1. Define trade mark, copyright and patents.

Q2. Mention the disintegration time for various tablet preparations as per I.P.

Q3. What is HEPA Filter. Define class 100 area.

Q4. Define intellectual property rights. Give its importance.

Q5. Mention types of glass used as containers

Q6. List the types of operations to be carried out in various grades for terminally sterilized products.

Q7. Mention the different size of hard gelatin capsules and its fill capacity

Q8. Mention the weight variation limit for capsules as per I.P.

Q9. Write a short note on distribution record.

Q10. Mention the frequency of periodic environmental monitoring for sterile preparations

a. particulate monitoring in air
b. Air rate changes
c. Air pressure Differential
d. temperature and humidity

## Section B

**II. ATTEMPT ANY TWO QUESTIONS. EACH QUESTION CARRIES TEN MARKS. (2X10=20)**

Q1. What is meant by IPQC? List various IPQC test for tablets and parenterals. Discuss any two IPQC test for tablets.

Q2. What is GLP? Enlist and discuss all the components of GLP.

Q3. Elaborate on cGMP requirements for industry location and surrounding, design, construction, sanitation, personnel, health and product recalls for pharmaceutical products.

**P.T.O.**

## Section C

**III. ATTEMPT ANY SEVEN QUESTIONS. EACH QUESTION CARRY FIVE MARKS. (7X5= 35)**

Q1.Explain scope of Q.C. and Q.A. Give overview of ICH guidelines.

Q2.List all the quality control test for parenteral finished products. Explain any two of the test.

Q3.Write a short note on quality auditing. Explain quality auditing plan and report. Discuss the key features of good warehouse practices.

Q4.Discuss the sanitation of manufacturing premises for sterile products.

Q5.Write a short note on animal house setup and its documentation.

Q6.What is SOP? Mention essential components and advantages of SOP.

Q7.Write a note on maintenance of store for raw material

Q8.Discuss the quality control testing of API.

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MQA-104 (T) Total No. of printed pages: 2

Roll No. | | | | | | | | | | |



# Odd Semester Carry over Examination 2019-20
## M.PHARMA (SEMESTER –I)
## PRODUCT DEVELOPMENT & TECHNOLGY TRANSFER

Time : 3:00 hr Max. Marks : 75

**Note: Attempt all questions.**

## SECTION-A

**ATTEMPT ALL 10 OBJECTIVE TYPE QUESTION.** **(10 X 2= 20)**

1. ICH-GCLP guidelines unified standard except for
   a. EU b. JAPAN c. USA d. INDIA
2. FDA define, which of the following area in aseptic processing
   a. Critical b. Manufacturing c. Packaging d. Cleaning
3. FDA established the ANDA as mechanism for review and approval of generic version
   a. 1955 b. 1960 c. 1965 d. 1970
4. Which is not the function of CDSCO
   a. Approval of clinical trial
   b. Licensing of blood bank
   c. Amendment of D & C Act
   d. Formulation of GMP certification scheme
5. Chemical name of Tween 60
   a. Polyoxyethylene sorbitan monolaurate
   b. Polyoxyrthylene sorbitan monopalmitate
   c. Polyoxyethylene sorbitan monostearate
   d. Polyoxyethylene sorbitan monooleate
6. Birefringence is
   a. Optical property c. Solubility property
   b. Chemical property d. Inducing property
7. Scientific scale up equipment should possess similarity
   a. Geometric b. Kinematic c. Dynamic d. All of these
8. In which of the following crystal having the $\alpha = \beta = \gamma = 90°$
   a. Tetragonal. b. orthorhombic c. cubic d. all of these

P.T.O

9. In which of the following is quantitative parameter of evlatluation

   a. Hardness  b. Friability  c. Thickness  d. *In-vitro* release

10. Which of the following packaging material used for secondary packaging

    a. Strip &b blister  b. Mono-carton  c. shipper  d. b & c both

## SECTION-B

**ATTEMPT ANY SEVEN QUESTION.** **(7 X 5 = 35)**

1. What are the clinical research, discuss about the various step in clinical research process.
2. List out the sources used in the investigation and development of ANDA.
3. Discuss about Pilot plant scale up the large scale manufacturing techniques.
4. Challenges occur during the scale up of new product development.
5. Qualitative and quantitative technology models for technology transfer.
6. Write the details about formula equipment, process, stability and quality control for syrups.
7. Describe the packaging of pharmaceutical and material used for packaging.
8. Write the Issues facing modern drug packaging and how they resolve.
9. Supplemental New Drug Application. Stability testing in product development.

## SECTION-C

**ATTEMPT ANY TWO QUESTION.** **(10 X 2 = 20)**

1. Define technology transfer, it's principle and how carry out from R& D to production. Write a note on documentation in technology transfer.
2. Importance of particle size and particle surface area in formulation development. What are the technique used in the study of crystal properties and Polymorphism?
3. Guideline for packaging of product as per CDSCO. Write a short not on BACPAC & USFDA

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