M. PHARM.

Q.A. I Sem.

2017 - 2018

M. Pharm (QA) New Syllabus

MQA-101T 1143

## Odd Semester Examination 2017-18

# M.PHARM. (PHARMACOGNOSY)(SEMESTER-I)

# MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

**Time: 03:00 Hours** **Max. Marks : 75**

Note: Attempt **any five** questions. All questions carry equal marks.

1. (a) Derive an expression for Beer-Lambert law. Discuss about the deviations from Beer-Lamberts law. (7.5)
   (b) Describe in detail the applications of UV-Visible spectroscopy. (7.5)
2. What are the different vibrational modes in Infrared spectroscopy? Describe the instrumentation and working of FT-IR. Give its merits and demerits compared to conventional Infrared spectroscopy. (15)
3. (a) Explain in detail the factors influencing chemical shift. (7.5)
   (b) Discuss the principle and instrumentation of proton NMR spectroscopy. (7.5)
4. Discuss the principle, instrumentation and applications of Gas Chromatography. (15)
5. (a) Explain the principle and applications of atomic absorption spectroscopy. (7.5)
   (b) Describe the factors which affect fluorescence efficiency. (7.5)
6. (a) Describe in detail the principle and instrumentation of Mass spectroscopy. (7.5)
   (b) Explain the general fragmentation patterns for the interpretation of organic compounds in Mass Spectroscopy. (7.5)
7. Write notes on: (**any three**) (5×3=15)
   (a) X-ray crystallography
   (b) Gel electrophoresis
   (c) Application of potentiometry
   (d) Ultra high performance liquid chromatography
8. (a) Compare HPLC and HPTLC techniques with respect to instrumentation and pharmaceutical application. (7.5)
   (b) Classify methods of thermal analysis. Discuss instrumentation and applications of DTA.

-----x-----

## Odd Semester Examination, 2017-18

## M.PHARMA. (SEMESTER-I)

# QUALITY MANAGEMENT SYSTEM

**Time: 03:00 Hours** **Max Marks: 75**

Note: Attempt **any five** questions. Each question carries **equal** marks.

1. What do you mean about Quality Management, write down its importance and also mention various dimensions of Quality?

2. Discuss the needs of drug stability testing and also mention the guidelines for stability testing of drug substance.

3. Discuss the various system inspection model :

   (a) Quality management system.

   (b) Production system.

   (c) Facility and Equipment system.

   (d) Laboratory control system.

4. What is bench marking process and also mention the merits and demerits of bench Marking process.

5. Write a short note on **any two** questions:

   (a) Quality Risk Management

   (b) Process development report

   (c) Importance of statistical Process control

6. Discuss the needs of a customer according to quality Management system and also enlist the factors affecting customer perception.

7. Write a short note on **any two** questions:

   (a) WHO Guidelines.

   (b) ICH –Q 9 Guideline

   (c) IPQC

*****

MQA-103T 1270

## Odd Semester Examination, 2017-18

## M.PHARMA. (SEMESTER-I)

# QUALITY CONTROL AND QUALITY ASSURANCE

**Time: 03:00 Hours** **Max Marks: 75**

**Note:** Attempt **all** questions, each question carries **equal** marks.

1. Discuss the role of Quality Assurance and Quality control in Pharmaceutical Industry and also mention its scope.

2. Explain the needs of Good Laboratory Practices and its scope regarding to pharmaceutical industry.

3. Write a short note on **any two** questions:

   (a) Master Batch Record.

   (b) Batch Manufacturing Record.

   (c) Controlled and Uncontrolled document .

4. What do mean by the term Intellectual Property Right and write an explanatory note on patents.

5. Discuss the Various documentation in Pharmaceutical Industry and how they are differ from each other.

6. Write a short note on any two questions:

   (a) Sanitation of manufacturing premises.

   (b) Mix-ups and cross contamination.

   (c) Expiry date calculation and calculation of yields.

7. What do you mean by process of sterilization and how sterile and non- sterile products are evaluated?

*****

## Odd Semester Examination, 2017-18

## M.PHARMA. (SEMESTER-I)

# PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

**Time: 03:00 Hours** **Max Marks : 70**

**Note** : Attempt **any five** questions. Each question carries equal marks.

1. Explain the various stages of Drug Development in detail.

2. Explain in detail about the significance design layout of pilot –plant scale–up study and also mention the pilot plant techniques of solid dosage forms.

3. What is preformulation study and also explain all the preformulation steps involved while developing new drug molecules .

4. Explain the Quality control test for **any two** :

   (a) Containers

   (b) Closures

   (c) Packaging material

5. What is the role of technology transfer in product development and also mention the Qualitative and Quantitative technology models.

6. Attempt **any two** question :

   (a) Techniques for study of crystal properties and polymorphism.

   (b) NDA and ANDA.

   (c) CDSCO and USFDA.

7. Describe the different packaging materials used for various products and how are they evaluated.

********