DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVESITY LONERE-RAIGAD-402103

End Semester Examination – Winter 2024

Course :Master of Pharmacy (Pharmaceutical Quality Assurance) Branch : Pharmacy

Semester : SEMESTER - 1

Subject Code & Name: MQA101T-MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Date:

Time : 3 Hours] **[Total Marks : 75**

Instructions to the Students:

1.All questions are compulsory.

2.Draw diagrams / figures wherever necessary

3.Figures to right indicate full marks

Q.1 Attempt any FIVE questions of the following (5 x 2) = 10

A) Give a comparative account on HPLC and UPLC. 2

B) Write the applications of Gel electrophoresis. 2

C) What is Normal phase & Reverse phase Chromatography? 2

D) What is Finger print Region? 2

E) Add a note on Interferences in Atomic Absorption Spectroscopy. 2

F) Enlist the advantages of Mass spectrometry. 2

G) Give a note on quenching of fluorescence. 2

Q.2 Attempt any FOUR questions of the following (5 x 4) = 20

A) Describe FT-IR. Enlist its advantages. 5

B) Elaborate electronic transitions in UV/Visible spectroscopy. Discuss solvent effect. 5

C) Explain types of crystals and applications of X ray diffraction.Discuss Bragg's law, different X-ray methods. 5

D) Explain Lambert-Beer Law. Discuss Deviation of Lambert-Beer Law. 5

E) Describe Time of Flight and Magnetic sector mass analyzer's. 5

F) Describe capillary electrophoresis. 5

Q.3 Attempt any THREE questions of the following (15 x 3) = 45

A) Explain modes of molecular vibrations and factors affecting vibrational frequencies. Give applications of IR spectroscopy. 15

B) Give block diagram of Mass spectrometer with function of each port. Describe various types of Mass analyzers. 15

C) Write in detail principle and instrumentation of gas chromatography. 15

D) Explain chemical shift, spin-spin coupling and factors affecting chemical shift. Give applications of NMR spectroscopy. 15

E) Enlist ideal properties of detector. Describe various pumps and detectors used in high performance Liquid chromatography. 15

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End Semester Examination – Winter 2024

Course :Master of Pharmacy (Pharmaceutical Quality Assurance) Branch : Pharmacy

Semester : SEMESTER - 1

Subject Code & Name: MQA102T-QUALITY MANAGEMENT SYSTEM

Date:

Time : 3 Hours] **[Total Marks : 75**

Instructions to the Students:

1.All questions are compulsory.

2.Draw diagrams / figures wherever necessary

3.Figures to right indicate full marks

Q.1 Attempt any FIVE questions of the following (5 x 2) = 10

A)	Define quality and dimensions of quality.	2
B)	Write the Objectives of Quality.	2
C)	Explain TQM.	2
D)	Describe WHO-GMP requirements.	2
E)	Write a difference between batch review and batch release.	2
F)	Define SPC and its importance.	2
G)	Enlist types of benchmarking.	2

Q.2 Attempt any FOUR questions of the following (5 x 4) = 20

A)	Give advantages of statistical control.	4
B)	Explain in detail the quality metrics of the pharmaceutical industry.	4
C)	Write a note on corrective and preventive actions.	4
D)	Describe elements of a PQS as per ICHQ10.	4
E)	Explain briefly the ISO guidelines.	4
F)	Explain quality metrics of the pharmaceutical industry.	4

Q.3 Attempt any THREE questions of the following (15 x 3) = 45

A)	Explain ICHQ8 in detail.	15
B)	Describe the concept of self-inspection.	15
C)	Explain in detail models of cost of quality.	15
D)	Explain the importance of the concept of IPQC in the pharmaceutical industry.	15
E)	Elaborate photostability testing of drugs and drug products.	15

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End Semester Examination – Winter 2024

Course :Master of Pharmacy (Pharmaceutical Quality Assurance) Branch : Pharmacy

Semester : SEMESTER - 1

Subject Code & Name: MQA103T-QUALITY CONTROL AND QUALITY ASSURANCE

Date:

Time : 3 Hours] **[Total Marks : 75**

Instructions to the Students:

1.All questions are compulsory.

2.Draw diagrams / figures wherever necessary

3.Figures to right indicate full marks

Q.1 Attempt any FIVE questions of the following (5 x 2) = 10

A) Write the role and responsibilities of CDER. 2

B) Write the scope and significance of Good laboratory Practices in ensuring quality and compliance. 2

C) Define Quality Assurance and write the scopes of QA. 2

D) Write the importance of hygiene as per cGMP. 2

E) Enlist the ICH Q series Guidelines. 2

F) Draw eCTD module. 2

G) Write the importance of SOP. 2

Q.2 Attempt any FOUR questions of the following (5 x 4) = 20

A) Write the cGMP guideline as per schedule M and their application in ensuring the pharmaceutical quality standards. 4

B) Discuss the three tier documentation procedure in Pharmaceutical industry. 4

C) Write in brief about CPCSEA guidelines. 4

D) Discuss the handling of waste and scrap disposal for manufacturing control. 4

E) Define patent and discuss the criteria for innovation to be patentable. 4

F) Explain production record review and change control. 4

Q.3 Attempt any THREE questions of the following (15 x 3) = 45

A) Discuss in detail process and finished product quality control test for solid dosage form. 15

B) Define and elaborate the concept of "Quality Assurance" and summarize the job responsibilities of head of "Quality Control" department and head of "Quality Assurance" department. 15

C) Describe the importance of Training in Pharmaceutical manufacturing. 15

D) Explain in detail BMR and GLP. 15

E) Discuss GMP contents as per Schedule M. 15

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End Semester Examination – Winter 2024

Course :Master of Pharmacy (Pharmaceutical Quality Assurance) Branch : Pharmacy

Semester : SEMESTER - 1

Subject Code & Name: MQA104T-PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

Date:

Time : 3 Hours] **[Total Marks : 75**

Instructions to the Students:

1.All questions are compulsory.

2.Draw diagrams / figures wherever necessary

3.Figures to right indicate full marks

Q.1 Attempt any FIVE questions of the following (5 x 2) = 10

A) What is supplemental new drug application (SNDA)? 2

B) What are different issues facing modern drug packaging? 2

C) What is enteral packaging? 2

D) What is aseptic packaging systems? 2

E) What is IND? 2

F) layout of pilot plant. 2

G) Types of glass used for pharmaceutical packaging. 2

Q.2 Attempt any FOUR questions of the following (5 x 4) = 20

A) Write a note on medical Device packing 5

B) What are Phase IV studies? How do they differ from Phase I/II/III clinicalstudies 5

C) Explain in detail stages of drug discovery and development. 5

D) Explain the quality control test for container and closures. 5

E) Write a note on ANDA 5

F) Discuss the challenges in scale up of new drug products. 5

Q.3 Attempt any THREE questions of the following (15 x 3) = 45

A) What are SUPAC and BACPAC? Discuss in detail SUPAC guidelines forchanges in formulation, site, equipment and process along with suitableexamples. 15

B) Explain solubility, Enlist methods to improve solubility and discuss in detailany one method to improve solubility of drug. 15

C) What is product registration? Discuss registration of bulk drugs and finishedformulations in India as per CDSCO. 15

D) Explain the concept of pre-formulation studies and discuss pre-formulationparameters for drug substance. 15

E) How is technology transferred from R & D to production? Give detailedoverview of various quantitative models in technology transfer. 15