M. PHARM.

Q. A. II Sem.

2017 - 2018

MQA-201T 2042

Even Semester Examination 2017-18

M.PHARMA. (Quality Assurance) (SEMESTER-II)

HAZARDS & SAFETY MANAGEMENT

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

Note : Answer any five questions in all.

Q.1	a.	Enumerate renewable and non-renewable resources.	(7.5)
	b.	Discuss various hazards related to radioisotopes.	(7.5)
Q2	a.	Discuss sources of chemical hazards and methods for controlling them	(7.5)
	b.	Discuss hazards during organic compound synthesis.	(7.5)
Q.3	a.	Discuss air circulation maintenance industry for sterile area and non sterile area.	(7.5)
	b.	What are the various strategies for fire prevention.	(7.5)
Q.4	a.	Explain management of over-Exposure to chemicals and TLV concept.	(7.5)
	b.	Explain the management of Toxic gases and Oxygen displacing gases.	(7.5)
Q.5		Discuss various approaches for management of fire and explosion.	(15)
Q.6		Explain ICH guidelines for environmental risk management.	(15)
Q.7		Short notes (any three) :	(15)
	a.	Factory act	
	b.	BOD	
	c.	COD	
	d.	Waste water treatment	
Q.8	a.	Discuss various self-protective measures against workplace hazards	(7.5)
	b.	Explain role of emergency services incase of accident	(7.5)

MQA-202T 2076

Even Semester Examination 2017-18

M.PHARMA. (Quality Assurance) (SEMESTER-II)

PHARMACEUTICAL VALIDATION

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

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

Q.1 Discuss the process employed for calibration of weights and measures. (15)

Q.2 a. Define the term Validation. (5)

b. Discuss Validation master plan. (10)

Q.3 Discuss types of Validation and validation process. (15)

Q.4 Give a detailed note on Qualification of UV-visible spectrophotometer. (15)

Q.5 Write a detailed note Qualification of Tabletting machine. (15)

Q.6 What is HVAC. Give a detailed note on HVAC validation. (15)

Q. 7 Explain the validation of analytical method as per ICH guidelines. (15)

Q.8 Give short note on (any three) : (15)

a. Economic importance of intellectual property

b. Factory acceptation test

c. Operational qualification

d. Cleaning in place

e. PTC A and convention patent application

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MQA-203(T) 2091

Even Semester Examination 2017-18

M.Pharm. (Quality Assurance) (SEMESTER-II)

AUDITS AND REGULATORY COMPLIANCE

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

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

Q.1 Discuss the management and responsibilities of audits. (7.5+7.5)

Q.2 Explain the role of quality as per cGMP. (15)

Q.3 a. Discuss the auditing of bulk pharmaceuticals. (7.5)

b. Discuss warehouse and weighing system. (7.5)

Q.4 Discuss the strategies in auditing process of microbiological laboratory. (15)

Q.5 Explain auditing process for HVAC system. (15)

Q.6 What is the need of auditing Water for injection system. Discuss the layout and steps involved in auditing Water for injection system. (5+10)

Q. 7 Discuss the strategies for auditing of granulation and tableting : (7.5+7.5)

a. Audit checklist for drug industry

b. Water in microbiology lab

c. Audit checklist for drug industry

d. Auditing of packaging material

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Even Semester Examination, 2017-18

M.PHARMA. (SEMESTER-II)

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

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

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

Q.1 Discuss the legal requirements and licenses for formulation industry (7.5+7.5)

Q.2 (a) Discuss storage requirement in a pharmaceutical plant. (7.5)

(b) Give a detailed note on production control. (7.5)

Q.3 Discuss manufacturing flowchart and IPQC for : (**any three**) (5×3=15)

(a) Dry powders

(b) Emulsion

(c) Ointments

(d) Small volume parental

Q. 4 Discuss cleaning in place and sterilization in place strategy in detail (7.5+7.5)

Q.5 (a) Discuss fluidized bed coating in detail (7.5)

(b) Discuss the problems encountered in tablet coating and methods to resolve them (7.5)

Q. 6 (a) Discuss stability aspect of packaging (7.5)

(b) Discuss advantages, disadvantages and current approaches with respect to QbD (7.5)

Q.7 How adopting the principles of PAT and QbD help in development of a better dosage form. Explain with two examples (15)

Q.8 Give short notes (**any three**) : (7.5×3=15)

(a) FFS technology

(b) Prefilled syringes

(c) Drug plastic interaction

(d) Formulation by Design

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