

M. PHARM.

D. A. II Sem.

2017 - 2018

## Even Semester Examination 2017-18

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

## HAZARDS &amp; 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)

## Even Semester Examination 2017-18

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

## PHARMACEUTICAL VALIDATION

Time: 03:00 Hours

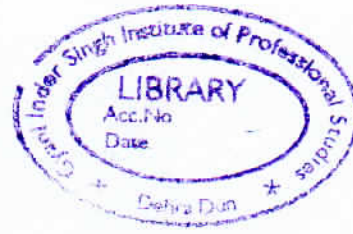
Max Marks : 75

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 Tableting 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 acceptance test
  - c. Operational qualification
  - d. Cleaning in place
  - e. PTC A and convention patent application

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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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**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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