March 2009

[KU 330] **Sub. Code: 2866**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

Branch V – PHARMACEUTICAL ANALYSIS

Paper IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262866

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. What are the different types of packaging material used in a pharmaceutical industry? Add a note on quality control of secondary packaging materials.

2. Give an account on concept and philosophy of TQM.

3. Write notes on the following:
   a) Quality audit of manufacturing process and facility.
   b) SOP for membrane filtration.
   c) Batch Release Document.

II. Write Short Notes : **(8 x 5 = 40)**

1. Write application of computers in quality control laboratory.
2. What is master formula record and write its importance in pharmaceutical industry.
3. When and how pharmaceutical products are recalled from the market?
4. Write a note on regulatory drug analysis.
5. Write the process and importance of patenting.
6. What criterias are considered while locating a pharmaceutical manufacturing facility?
7. What protocols are followed while selecting vendors?
8. Write the salient features of consumer protection act.

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September 2009

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Q.P. Code : 262866

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. a) Write a detailed note on concepts and philosophy of ISO – 9000.
   b) How the sanitation and sterile areas are maintained in pharma industry?

2. a) What are methods and equipment involved for dry heat sterilization?
   b) How the quality control of packing material is achieved?
   c) What are the tests to be performed for assuring quality of glass?

3. a) Write notes on purchase specifications for raw materials.
   b) Give an account on standard operating procedures.
   c) Write about the training of personnel.

II. Write Short Notes : **(8 x 5 = 40)**

1. What are various types of plastics used as packing materials?
2. Discuss concepts of Good Laboratory practice with suitable examples.
3. Explain the concepts of auditing with special reference to loan license.
4. How the recovered goods are handled?
5. Write a note on recent amendments in drug and cosmetics act.
6. What are the advantages and disadvantages with the globalization of drug industry?
7. Describe the regulatory aspects of pharmaceuticals and bulk drug manufacturing.
8. Give an account on loan licensing auditing.

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March 2010

[KW 330] **Sub. Code: 2866**

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(Regulations 2006)

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FIRST YEAR

Branch V – PHARMACEUTICAL ANALYSIS

Paper IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262866

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. a) Write a detailed note on concepts and philosophy of Total quality management.
   b) Give a detailed account on location and building requirements for pharma industry.

2. a) What do you understand by SOP? What are its salient features for a manufacturing process?
   b) Explain the significances of SOP.
   c) Write about the training of personnel.

3. What are the protocols to be followed in selecting vendors? Add a note on Purchase, receipt, storage, and release of raw materials.

II. Write Short Notes : **(8 x 5 = 40)**

1. Discuss concepts of good laboratory practice with suitable examples.
2. Give an account on quality audits of manufacturing processes and facilities.
3. Give an account on key provisions under united states GLP regulations for non-clinical testing laboratory.
4. Discuss the salient features of environmental protection act.
5. What is master formula? What are its components?
6. Describe the regulatory aspects of pharmaceuticals and bulk drug manufacturing.
7. Give an account of good ware housing practice.
8. Give an account on standard operating procedures for compression.

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