UKA TARSADIA UNIVERSITY
M.PHARM Ist Semester Examination- January 2012
Subject Name: Industrial Pharmacy Practice
Subject Code: 040040103

Max. Marks: 70

Instructions:
1. Attempt all questions.
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks.
5. Draw diagrams/figures whenever necessary.

Section-I

Q-1 (A) Do as directed: **[07]**

(I) List different categories of compressed air.
(II) Write the significance of preparation and maintenance of records for an industrial process.
(III) Draw design of master production and control records.
(IV) Write the area requirement for small and large volume parenterals.
(V) Define master manufacturing formula. What information does it contain?
(VI) Draw typical flow diagram for the handling of materials from supplier to the dispensary.
(VII) Specify the time period for maintenance of the complaint's file.

Q-1 (B) Answer the following in brief: (Any 4) **[08]**

(I) What is the demarcation of black, grey and white rooms in clean room for manufacturing of sterile products?
(II) What are the temperature, humidity and differential pressure requirements between areas of different environmental standards?
(III) Highlight the importance of quarantine area in stores.
(IV) How can the integrity of individual pack strips be checked?
(V) Highlight the importance of dust collection system.
(VI) What are the features of ultrafilteration technique for purification of water?

Q-2 Answer the following: **[10]**

A) Discuss in detail about minimum area requirement and equipment recommended for manufacturing of tablet dosage form.

OR

A) Discuss in detail about fluid bed coaters.
B) Describe the process plan for preparation and packaging of sugar coated tablet using wet granulated methods.

OR

B) Write a note on pharmaceutical factory location.

Q-3 Answer the following in detail. (Any 2) **[10]**

A) Discuss about batch manufacturing record.
B) Describe the qualities of environmental air required for pharmaceutical industry.
C) Give the layout of oral liquids and describe the flow of materials.

Section-2

Q-4 (A) Do as directed: **[07]**

(I) What is passivation?
(II) Define inventory.
(III) Write full form of HEPA & ULPA.
(IV) What is line clearance?
(V) What are internal quality audits?
(VI) What are SOPs?
(VII) What color labels are used for under test, rejected and approved goods in stores?

Q-4 (B) Answer the following in brief: (Any 4) **[08]**

(I) Write formula for EOQ and explain the terms
(II) Enlist any four parameters that need to be evaluated during scale up of suspensions.
(III) Write working principle of Versator.
(IV) What is a master formula? Enlist its content.
(V) Enlist the various types of documents required in a pharmaceutical company.
(VI) Discuss the points to be considered while making a good SOP.

Q-5 Answer the following: **[10]**

A) Proper implementation of cGMP in pharmaceutical industry will ensure that quality is "built in" in a pharmaceutical product. Comment

OR

A) List various techniques of inventory control. Explain ABC concept.

B) Describe the GMP guidelines for premises of a pharma manufacturing plant.

OR

B) Explain operational aspects and requirements for pilot plant and scale up technique.

Q-6 Answer the following in detail. (Any 2) **[10]**

A) Write a SOP for the operation of a double cone blender.
B) Write a note on pricing of stock.
C) Discuss scale-up considerations for tablet dosage forms.