UKA TARSADIA UNIVERSITY

M.Pharm. (Pharmaceutics) / M.Pharm. (PT) (1st Semester)

Subject Code : 040040103/040120103 **Subject :** Industrial Pharmacy Practice

Duration: 3 Hours **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 allocated to that question.
5. Draw diagrams/figures whenever necessary.

Section-1

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

1. Enlist various categories of compressed air.
2. Why airlock system is required in pharmaceutical industry?
3. Give full form of IPQC.
4. What do you mean by quarantine area in Pharmaceutical Industry?
5. What is "gray area" in pharmaceutical industry?
6. Define class 100 area for sterile products.
7. Write the area requirement for small and large volume parenterals.

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

1. Explain contamination and cross-contamination.
2. Enlist various objectives of Schedule M.
3. Enlist the importance of dust collection system.
4. Enlist ideal characteristics of clean room.
5. Enlist importance of HVAC system in pharmaceutical industry.
6. How can the integrity of individual pack strips be checked?

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

A. Draw a simple layout of pharmaceutical production plant along with F & D section?

OR

A. Discuss in details FB Coaters.

B. With a neat sketch, explain the qualitative and quantitative layout of liquid oral department.

OR

B. Write short note on equipments required for Sterile Manufacturing as per schedule M.

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

1. Describe the equipments required in the manufacture of solid dosage forms as per Schedule-M.
2. Explain departmental layout with specific requirement of equipments for oral liquid dosage forms.
3. Write a note on utility services required for a pharmaceutical manufacturing unit.

Section-2

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

1. Differentiate between quality control & quality assurance.
2. What should be minimum pressure required between different environmental area?
3. How many numbers of tablets are to be compressed for pilot scale batch?
4. What is meaning of pilot plant scale up?
5. What are the 5M's required for manufacturing of a product?
6. What information should be mentioned on label of a finished product?
7. What are SOPs?

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

1. Enumerate various types of documents.
2. Discuss the points to be considered while making a good SOP.
3. Define production planning.
4. Enlist importance of pilot plant scale up.
5. Define the term BMR and BPR.
6. Enlist the responsibilities of personnel as per GMP.

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

A. Discuss space requirements in a pilot plant

OR

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

B. List various techniques of inventory control. Explain ABC concept.

OR

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

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

1. Write a SOP for the operation of a double cone blender.
2. Write a note on pricing of stock.
3. Dr. Shetty prepared 10 lakh Ofloxacin 200mg tablet in the manufacturing unit. Prepare batch manufacturing record for manufacturing of tablet dosage form. secion 2