

UKA TARSADIA UNIVERSITY
M.PHARM Ist Semester Examination December 2012
Subject Name: Industrial Pharmacy Subject Code: 040040103/ 040120103

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) Enlist any two high shear granulators.
- (II) Enlist water & oil soluble preservatives.
- (III) Enlist equipments required for manufacturing of liquids as per Schedule M.
- (IV) What are the temperature & pressure requirements for moist heat sterilization?
- (V) Define plant location.
- (VI) Define plant layout.
- (VII) Define working capital.

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

- (I) Enlist types of plant layout. Which type of layout is used in pharmaceutical industries & why?
- (II) What is cross over traffic in layout? Enlist its advantages & disadvantages.
- (III) Specify the dimensions of B & D type tablet tooling.
- (IV) Discuss in brief about the garments to be worn by a personnel working in parenteral area.
- (V) Describe in brief working of triple roller mill.
- (VI) What is A, B, C & D areas as per Schedule M with reference to parenteral products?

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

A) Describe the qualitative and quantitative layout for enteric coated tablets.

OR

A) Explain with a neat sketch the qualitative and quantitative layout for creams.

B) Mr. Anand wants to establish a pharmaceutical industry in Gujarat. What points needs to be considered by him for selecting a suitable factory location?

OR

B) Describe the equipments required in the manufacturing of hard gelatin capsules as per Schedule M

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

- A) Describe a qualitative and quantitative layout for dry powder for injection.
- B) Describe in detail about the fluid bed processor.
- C) Write a note on utilities in a pharma manufacturing plant.

Section-2

Q-4 (A) Do as directed:

[07]

- (I) What are the different color labels used for identifying approved, rejected & under test materials in a warehouse?
- (II) Enlist different types of inventories.
- (III) How many types of spray patterns are available in fluid bed processors?
- (IV) What are A, B & C items in ABC concept of inventory management?
- (V) Draw a status label affixed outside the manufacturing area.
- (VI) Enlist steps required for aseptic filling of a parenteral product.
- (VII) Write full forms of cGMP & ICH.

Q-4 (B) Answer the following in brief: (Any 4)

[08]

- (I) Enlist activities that can be performed in black, grey & white area of parenterals.
- (II) Enlist steps involved in lyophilization of a product.
- (III) Enumerate difference between pilot plant & scale up operation.
- (IV) Explain in brief about production scheduling.
- (V) Enlist contents of a BMR.
- (VI) Enlist techniques of inventory management.

Q-5 Answer the following:

[10]

- A) Reva Pharmaceuticals has a yearly consumption of 25,000 glass bottles for liquids. The unit cost of each bottle shell is Rs. 5. The cost of carrying inventory is 10% per year. Ordering cost is Rs. 60 per order. At what number of inventory is the ordering and carrying cost similar? Explain applications and limitations of Economic order quantity.

OR

- A) Enlist the advantages of making an SOP. Write SOP for operation of a capsule filling machine.
- B) Discuss necessity of engineering department, QA and administration office in a pilot plant.

OR

- B) Discuss the operation, application, advantages & disadvantages of octagonal blender & screw blender.

Q-6 Answer the following in detail. (Any 2)

[10]

- A) Enlist objectives of pilot plant activity. Discuss scale up considerations for dispersible tablets.
- B) Write a note on cost management.
- C) Levofloxacin Tablets (100 nos.) are to be packed in each HDPE bottle. Write a BPR of this product.