Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Remedial Examination April 2010

Subject code: 910202 **Subject Name: Industrial Pharmacy**

Date: 07 / 04 / 2010 **Time: 12.00 noon – 03.00 pm**

Instructions: **Total Marks: 80**

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1 (a) Write the list of documents with their importance that is attached to BMR. **06**

(b) What do you understand by layout of a pharmaceutical firm? Explain advantages & disadvantages of various types of layouts. **05**

(c) Suppose you want to open a large scale-manufacturing unit, for production of liquid orals, tablets and small volume parenterals. What kind of layout will be most preferred and why? Draw a detailed rough layout of the plant and demarcate the white, gray and black zone according to the GMP guidelines. **05**

Q.2 (a) Write a note on cGMP guidelines pertaining to Equipments. **06**

(b) Explain format, writing styles and content of SOP with illustration of a SOP for Rotary Tablet Machine. **05**

(c) Explain any one equipment required in manufacture of solid dosage forms as per schedule –M. **05**

Q.3 (a) ABC Pharmaceuticals is planning to launch a tablet formulation of new drug (X) in market. The product development in R&D has been completed. The formula and procedure (in brief) used in R&D is as given below. **06**

S. No.	***Ingredient***	***Qty/Tablet***	***Qty/Batch***
1	Drug	500 mg	500 g
2	MCC	250 mg	250 g
3	Starch Paste (12.5% w/w)	10 mg	10 g
4	Starch	15 mg	15 g
5	Talc	3 mg	3 g
6	Magnesium Stearate	3 mg	3 g

Supposing that you have been asked to scale-up the process prospectively, what will be your scale up and production batch size? Give the detailed step wise procedure as to how you will scale-up the above mentioned process with in-process tests that you will be carrying out at each step.

	(b)	Explain qualitative and quantitative departmental layout with specific requirement of equipments for sterile dosage forms.	**05**
	(c)	Explain the preparation of Batch Manufacturing Record with illustration of BMR for a tablet batch.	**05**
Q.4	(a)	Discuss documentation guidelines as per GMP.	**06**
	(b)	Explain typical unit operations involved in manufacture of solid dosage forms.	**05**
	(c)	Describe the importance of personnel facilities in a pharmaceutical unit.	**05**
Q.5	(a)	Write a note on validation protocol for a pharmaceutical process.	**06**
	(b)	How will you prepare qualitative and quantitative departmental layout with equipments required for liquid dosage forms?	**05**
	(c)	Write a note on Batch Packing Record.	**05**
Q. 6	(a)	Write a note on HVAC facilities in a pharmaceutical unit.	**06**
	(b)	Write a detailed note on concept used for planning and scheduling production.	**05**
	(c)	Proper implementation of GMP in pharmaceutical plants across the nation will serve quality pharmaceutical product to people. Comment.	**05**
Q.7	(a)	Describe the equipments required in the manufacture of semi-solid dosage forms as per Schedule-M.	**06**
	(b)	Explain GMP guidelines for packaging and labelling controls.	**05**
	(c)	Discuss various factors to be considered to set up a new sterile dosage form manufacturing unit with reference to location and utility facilities.	**05**

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