**Seat No.: _____** **Enrolment No._____**

**GUJARAT TECHNOLOGICAL UNIVERSITY**

**M. Pharm. – SEMESTER– I • EXAMINATION – SUMMER-2016**

**Subject code: 910108** **Date: 27/05/2016**

**Subject Name: Industrial Pharmacy – I**

**Time: 10:30 AM to 1:30 PM** **Total Marks: 80**

**Instructions:**

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

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|---|---|---|---|
| **Q.1** | **(a)** | Discuss Personnel facilities in context to GMP. | **06** |
| | **(b)** | Prepare qualitative and quantitative department layout with equipments for manufacture of Compressed Tablets. | **05** |
| | **(c)** | Explain the importance of IPQC in Pharmaceutical Industry. Enlist IPQC tests for solid dosage forms and semisolid products. | **05** |
| **Q.2** | **(a)** | Enumerate the requirements for plant and equipment for manufacture of External preparations in context to revised schedule M and discuss principle, construction and working of Colloid mill. | **06** |
| | **(b)** | Discuss BMR in context to GMP. | **05** |
| | **(c)** | Write short note on SOP and SOP. | **05** |
| **Q.3** | **(a)** | Discuss the role of technology of indoor environmental control in pharmaceutical Industry in context to GMP. | **06** |
| | **(b)** | Define GMP and explain its importance in pharmaceutical production. Give full form of following abbreviations:<br>(i) ICH (ii) MHRA (iii) CFR (iv) MCC (v) TGA and (vi) EUGMP | **05** |
| | **(c)** | Write a note on types of plant layout. | **05** |
| **Q.4** | **(a)** | Discuss various dust collecting systems used in pharmaceutical Industry. | **06** |
| | **(b)** | Write short note on Validation protocol. | **05** |
| | **(c)** | Write a note on PAT. | **05** |
| **Q.5** | **(a)** | Mention the requirements of plant and equipments for manufacture of Parenteral preparations in context to revised schedule M. | **06** |
| | **(b)** | Explain line clearance and reconciliation of labels, cartoons and other packaging materials in context to GMP. | **05** |
| | **(c)** | Prepare quantitative layout for manufacture of liquid preparation. | **05** |
| **Q. 6** | **(a)** | Discuss in detail principle, working and construction of Fluid bed dryer. | **06** |
| | **(b)** | Write SOP for Liquid oral filling operation. | **05** |
| | **(c)** | Write short note on Complaints and Recalls in context to GMP. | **05** |
| **Q.7** | **(a)** | Discuss various precautions against mix-up and cross-contamination in pharmaceutical production in context to pharmaceutical manufacturing and controls under GMP. | **06** |
| | **(b)** | Discuss the responsibilities of Quality control unit and personnel qualifications in context to Organization and personnel under GMP. | **05** |
| | **(c)** | Discuss monitoring of various environmental parameters in context to Manufacture of sterile products. | **05** |

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