

Roll No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**PARUL UNIVERSITY**  
**PARUL INSTITUTE OF PHARMACY AND RESEARCH**  
**B.PHARM SEVENTH SEMESTER**  
**FIRST INTERNAL THEORY EXAMINATION: 2022-23**

**Subject Name: Industrial Pharmacy II**

**Date: 19/7/22**

**Subject Code: BP702T**

**Time: 7:45-9:00 am**

**Total Marks: 30**

**Q.2** Long Answers: (Any One)

- 1) Define a pilot plant. Describe the general requirements for a pilot plant. **10**
- 2) Describe the space requirements for a pilot plant. What are the primary concerns in material handling of a pilot plant manufacturing tablet? **10**

**Q.3** Short Answers: (Any Two)

- 1) Write the checklist points of GMP in a scale up process. **05**
- 2) Write role of regulatory affairs department. **05**
- 3) Define Quality Risk Management. Write a note on various steps involved in QRM. **05**

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**Instructions:**

1. Figures to the right indicate full marks.
2. Make suitable assumptions wherever necessary.

**Q.1 Multiple Choice Questions:**

- |             |   |           |
|-------------|---|-----------|
| <b>(1)</b>  | There are _____ phases for clinical trial<br>(a) 2 (b) 3 (c) 4 (d) 5  | <b>01</b> |
| <b>(2)</b>  | Food, Drug and Cosmetic act comes in force since<br>(a) 1938 (b) 1940 (c) 1945 (d) 1948   | <b>01</b> |
| <b>(3)</b>  | Drug Development team connect with<br>(a) Regulatory department (b) Clinical department<br>(b) Scientific affairs (d) All of above  | <b>01</b> |
| <b>(4)</b>  | A small-scale industrial plant in which problems can be identified and solved before the full-scale plant is built is called<br>(a) Scale up (b) Pilot plant<br>(c) Commercial plant (d) Bioplant   | <b>01</b> |
| <b>(5)</b>  | Which of the following is not an objective of pilot plant study<br>(a) Evaluates the production and process controls<br>(b) Issues related to support Current Good Manufacturing Practices<br>(c) Factors the requirements, training, and responsibilities of personnel<br>(d) Not to develop and validates the product reprocessing procedures | <b>01</b> |
| <b>(6)</b>  | The minimum space requirements in a pilot plant is<br>(a) 3 (b) 4 (c) 5 6(d)  | <b>01</b> |
| <b>(7)</b>  | The processing technicians should understand the<br>(a) Manufacturing directions (b) Weight sheet<br>(c) Sampling directions (d) All of the above   | <b>01</b> |
| <b>(8)</b>  | The transfer of technology between sites of different companies is called as ---<br>(a) Inter-company transfer (b) Intra-company transfer<br>(c) Technology transfer (d) Technology transfer protocol   | <b>01</b> |
| <b>(9)</b>  | The basic requirement of Technology Transfer is .....<br>(a) Sending Unit (SU) (b) Receiving Unit (RU)<br>(c) Both (a) and (b) (d) None of these )  | <b>01</b> |
| <b>(10)</b> | The discipline of any organization involved in transferring of designated process or method is called as .....<br>(a) SU (b) RU (c) QRM (d) None of these   | <b>01</b> |