

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM – SEMESTER -1 - EXAMINATION – WINTER - 2018

Subject Code: 910204**Date: 05/01/2019****Subject Name: Good manufacturing and Good Laboratory Practice****Time :10:30 AM TO 01:30 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) | Describe concepts of QA& GMP. | 06 |
| | (b) | Describe in detailed general consideration for factory premises. | 05 |
| | (c) | Write general guidelines given for personnel selection and training. | 05 |
| Q.2 | (a) | Write short note on cleaning, maintenance and sterilization of Equipment. | 06 |
| | (b) | Write brief note on Selection of vendor | 05 |
| | (c) | Write note on master batch documents for tablet dosage form. | 05 |
| Q.3 | (a) | Write an account of Good Warehouse Practices | 06 |
| | (b) | Write a short note on in process quality controls of sterile dosage forms. | 05 |
| | (c) | Write short note on Quality Audit. | 05 |
| Q.4 | (a) | Discuss line clearance regarding packaging and labeling control. | 06 |
| | (b) | What are reserve samples? Discuss briefly their significance. | 05 |
| | (c) | Write a note on Testing and release of finished product. | 05 |
| Q.5 | (a) | Describe waste and scrap disposal procedures. | 06 |
| | (b) | Write note on complaint & product recall. | 05 |
| | (c) | Write a short note on GLP. | 05 |
| Q. 6 | (a) | Describe the elements with significance of WHO certification scheme. | 06 |
| | (b) | Describe the raw material specifications with suitable examples. | 05 |
| | (c) | Testing of packaging materials. | 05 |
| Q.7 | (a) | What are SOPs? Give objectives of SOP. Enumerate the topics of SOP. Describe the general format for SOP. | 06 |
| | (b) | Write a note on Good Distribution Practices | 05 |
| | (c) | Write a note on Self Inspection | 05 |
