

**GUJARAT TECHNOLOGICAL UNIVERSITY****M. PHARM. - SEMESTER – I • EXAMINATION – WINTER 2012****Subject code: 1911601****Date: 09-01-2013****Subject Name: eGMP and Documentation****Time: 10.30 am - 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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| <b>Q.1</b>  | (a) Describe concepts of QA, GMP and GLP in brief.   | <b>06</b> |
|             | (b) Discuss the general guideline for personnel selection, training and hygiene.   | <b>05</b> |
|             | (c) What do you mean by utility services? Enlist them and write a note on any one of them in brief.  | <b>05</b> |
| <b>Q.2</b>  | (a) Write a note on cleaning, sanitization & sterilization of equipments.  | <b>06</b> |
|             | (b) What is importance of purchase specifications and maintenance of store for raw materials?  | <b>05</b> |
|             | (c) Define SOP. Enlist the objectives of SOP. Explain format of SOP.   | <b>05</b> |
| <b>Q.3</b>  | (a) Give a standard format of master formula record.   | <b>06</b> |
|             | (b) Write a SOP for any one unit operation used in production.   | <b>05</b> |
|             | (c) Give a layout of batch manufacturing records in general.   | <b>05</b> |
| <b>Q.4</b>  | (a) What is IPQC? Explain IPQC test for tablet manufacture.  | <b>06</b> |
|             | (b) Describe the cGMP requirements for packaging and labeling requirements.  | <b>05</b> |
|             | (c) What is a pharmaceutical warehouse? Discuss briefly the good warehousing procedures.   | <b>05</b> |
| <b>Q.5</b>  | (a) Enlist the types of documents made in quality assurance department of pharmaceutical industry. What is specification and what information's it contains? | <b>06</b> |
|             | (b) Write a short note on Sampling plans for starting materials, packaging materials and finished products.  | <b>05</b> |
|             | (c) Write a note on distribution records <b>OR</b> complaint & product recall.   | <b>05</b> |
| <b>Q. 6</b> | (a) Define GLP. Explain the key points in GLP.   | <b>06</b> |
|             | (b) Write a short note on waste disposal and scrap disposal procedures.  | <b>05</b> |
|             | (c) Write a note on WHO certification scheme for pharmaceutical products.  | <b>05</b> |
| <b>Q. 7</b> | (a) Write a note on Quality audit and self inspection in pharmaceutical industry.  | <b>06</b> |
|             | (b) Explain the scope of USFDA regulations. Discuss the preparations required for facing USFDA audit.  | <b>05</b> |
|             | (c) Discuss the tests carried out on plastic packaging materials.  | <b>05</b> |

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