

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm - SEMESTER-I • EXAMINATION – SUMMER-2015****Subject Code:1911601****Date:21/05/2015****Subject Name: cGMP and Documentation****Time:02:30 PM to 05:30 PM****Total Marks: 80****Instructions:**

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

- Q.1** (a) Discuss the role and significance of QA in manufacturing of Pharmaceuticals. **06**
(b) What is GLP? Describe in brief scope, objectives and fundamentals of GLP. **05**
(c) Write a short note on personnel and training. **05**
- Q.2** (a) Give an account of control of contamination. **06**
(b) Explain design and construction features with reference to aseptic processing. **05**
(c) Outline the general consideration in equipment cleaning and maintenance. **05**
- Q.3** (a) Discuss the factors to be considered for selection of equipment. **06**
(b) Describe the procedure of vendor selection. **05**
(c) Write a note on raw material purchase specification. **05**
- Q.4** (a) Enumerate basic types of quality audits and discuss reasons for quality audits. **06**
(b) Enumerate types of documents. Describe the general guidelines to be followed for design and use of documents. **05**
(c) Write in brief on format of SOP. **05**
- Q.5** (a) What do you mean by In Process Quality Control? Discuss its role in context to cGMP. **06**
(b) Write a short note on ICH guideline. **05**
(c) Discuss line clearance and reconciliation of packing materials in context to the cGMP. **05**
- Q.6** (a) Write a brief note on sampling plan to control product quality. **06**
(b) Discuss the role and responsibility of quality control laboratories. **05**
(c) Enlist the packaging material used for the parenteral products and write about testing of any one of that packaging material. **05**
- Q.7** (a) Write in brief on evaluation of complaints. **06**
(b) Describe Waste disposal procedures and its records. **05**
(c) Write a note on specification of finished products. **05**
