

C.U.SHAH UNIVERSITY

Winter Examination-2018

Subject Name: Quality Control and Quality Assurance

Subject Code: MQA103T

Branch: M.Pharm (QA)

Semester: 1 Date : 30/11/2018

Time : 02:30 To 05:30

Marks : 70

Instructions:

- (1) Use of Programmable calculator & any other electronic instrument is prohibited.
- (2) Instructions written on main answer book are strictly to be obeyed.
- (3) Draw neat diagrams and figures (if necessary) at right places.
- (4) Assume suitable data if needed.

Q-1 Attempt the following questions: (20)

- a) GMP
- b) Quality Control
- c) Quality Assurance
- d) Sterilize in Place
- e) Clean in Place
- f) Trade mark
- g) Copyright
- h) Patents
- i) eCTD
- j) Expiry date calculation

Attempt the following questions:

Q-2 Attempt any two of following : (20)

- | | | |
|----------|---|-----------|
| A | Enumerate GLP guidelines practiced in India and briefly explain scope of GLP activities | 10 |
| B | What is meant by SOP? Describe any two SOPs used in production department. | 10 |
| C | Explain the principles of plant layout and construction with referenceto manufacture of parenteralgiving plan diagram | 10 |

Q-3 Attempt any Seven of following : (35)

- | | | |
|----------|--|----------|
| A | Explain the procedures for recalling a product | 5 |
| B | Write different tests and methods for testing of primary packing materials. | 5 |
| C | Write the contents & interrelationship between Master Manufacturing , BatchManufacturing & Batch Packing records | 5 |
| D | Write a note on purchase specifications and maintenance of stores forrawmaterials | 5 |
| E | Write a note on WHO CertificationScheme | 5 |
| F | Write note on waste & scrap disposal | 5 |
| G | Describe the in-process quality checks performed on tablets. | 5 |
| H | Outline GLP guideline for animal house facility and animal care in a non-clinical testing laboratory | 5 |
| I | What are cGMP guidelines for recruitment of technical staff in pharmaceutical manufacturing area? | 5 |

