

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

**PARUL UNIVERSITY**  
**PARUL INSTITUTE OF PHARMACY**  
**B.PHARM SIXTH SEMESTER**  
**SECOND INTERNAL THEORY EXAMINATION: 2020-21**

Subject Name: Quality Assurance

Subject Code: BP606T

Time: 2:00 pm – 3:15 pm

Date: 13/03/2020

Total Marks: 30

**Instructions:**

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

**Q.1 Multiple Choice Questions:**

[10]

- |   |    |
|---|----|
| (1) Good manufacturing Practice is concerned with<br>(a) Production (b) Quality control<br>(c) Both (d) None  | 01 |
| (2) EMS stands for<br>(a) Environmental management system<br>(b) Employees management system<br>(c) Engineering management system<br>(d) Equipment management system  | 01 |
| (3) ISO 14001:2004 covers guidelines for<br>(a) EMS - Complete guidelines for environmental Auditing<br>(b) EMS - Guidance with the specification for use<br>(c) EMS - Complete guidelines for Qualification criteria for environmental Auditors<br>(d) EMS - Evaluation of environmental performance                     | 01 |
| (4) NABL stands for<br>(a) National Accreditation Board for Testing and Calibration Laboratorie<br>(b) National Assurance Board for Testing and Calibration Laboratories<br>(c) Nationality Assurance Board for Testing and Calibration Laboratories<br>(d) National Assurance Board for Testing and Central Laboratories | 01 |
| (5) Which is not the tool of QbD from following?<br>(a) Risk assessment (b) Design of Experiment<br>(c) Process Analytical technology (d) Quality management system   | 01 |
| (6) Class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.<br>(a) Class I, (b) Class II, (c) Class III, (d) Class IV  | 01 |
| (7) Below are the types of complain except<br>(a) Quality complaints (b) Adverse reaction complaints<br>(c) Employee complaints (d) Other medically related problems  | 01 |
| (8) Technical investigation of complains involves<br>(a) Documents based investigation, (b) Laboratory analysis of retain sample<br>(c) Laboratory analysis of complaint sample, (d) All of above   | 01 |
| (9) To notify the consumers about the recall of a product, following are the means except<br>(a) Radio broadcast (b) Telephonic call (c) TV News (d) News Paper   | 01 |
| (10) A bottle of aspirin tablets contains 90 tablets instead of 100 as mentioned on label. So what class of recall it would be?<br>(a) Class I, (b) Class II, (c) Class III, (d) Class IV   | 01 |

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

- (1) Write in detail about Organization and Premises as per GMP guideline. **10**
- (2) Draw a flow chart on Handling Customer complaints and explain the procedure in detail. **10**

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

- (1) Write a short note on Elements and tools of QbD. **05**
- (2) Define (i) Customer (ii) Trend Analysis (iii) Confirmed complaint (iv) Substandard quality (V) Types of recall **05**
- (3) Write a short note on Recall Classification. **05**

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