

2016

**P.G. Diploma Examination in
Quality Control and Assurance in
Microbial Technology**

1st Semester Examination

PAPER—QUA-103

Full Marks : 50

Time : 2 Hours

The figures in the right-hand margin indicate full marks.

*Candidates are required to give their answers in their
own words as far as practicable.*

Illustrate the answers wherever necessary.

Group—A

[Marks : 25]

Answer any *five* questions.

1. (a) Briefly describe a method for long-term preservation of a live bacterial specimen.

(Turn Over)

- (b) Mention with examples, the importance of such preservation. 3+2
2. Illustrate the working principle and use of Laminar flow-hood in a microbiology laboratory. 3+2
3. Enumerate the basic guidelines for safe handling of chemicals in a laboratory. 5
4. Write down the various level of Biosafety. Give one example of microorganisms in each case. 5
5. If your laboratory is contaminated with a particular micro-organism, how will you identify its source and how will you control it? 3+2
6. Write a short note on Lab-Biosafety manual by WHO (2004). 5
7. Focus on the Indian Biosafety rules and its regulations. 5
8. Give a brief account of proper disposal procedures of biohazardous wastes. 5

Group—B

[Marks : 25]

Answer any *five* questions.

1. What do you mean by API? How can you maintain the quality of pharmaceutical products, explain with suitable examples. 2+3
2. Mention the steps taken for drug validation. Mention any three critical steps that can affect validation (if not performed). 3+2
3. Elucidate the needs of quality control (QC) in an industry, with appropriate examples from industrial product(s). 3+2
4. Define GMP. State the basic requirements of GMP. 2+3
5. How statistical sampling methods affect the quality testing? Give suitable reasons to your answer. 3+2
6. What is the difference between quality assurance and quality control in an industry? 5

7. Mention the quality criteria managements undertaken for an ISO 9000 certified company. 5
8. What do you mean by bulk drugs ? State the precautions taken to control their quality. 2+3
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