2015

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.

Answer any *Five* Questions from each Group.

Group—A

[*Marks : 25*]

Answer any *five* questions.

1. (a) Describe the important differences between a fume hood and a biological safety cabinet.

   (b) Describe what safety arrangements must be available in the laboratory for the disposal of 'sharps' (needles, scalpels, microscope slides and cover slips etc.) 3+2

2. (a) In respect of safety norms, what are the purpose and use of the biohazards symbol ?

   (b) If a fermentation project is scaled up from 3L to 30L, can this change the biosafety level of this project ? Give reasons. 2+3

3. (a) What is meant by biosafety level ?

   (b) Illustrate how containment is related to biosafety level.

   $2\frac{1}{2}+2\frac{1}{2}$

4. What is MSDS ? What are information included in a MS data sheet ? 5

5. What do you mean by biological hazards ? Describe the disposal ways of such hazards. 5

6. Write a short note on : 'Indian Biosafety Rules and Regulations'. 5

7. Describe the safety producers for the laboratories those are handling with Radioactive molecules and Radiation technology. 5

8. Write short notes on (any *one*) : 1×5

   (a) Occupational Healthy Safety ;

   (b) EHS ;

   (c) Biomedical Waste Rules 2011 under the Environmental (Protection) Act' 1986.

Group—B

[*Marks : 25*]

Answer any *five* questions.

1. What are bulk drugs and how are they related to dosage forms ? Illustrate with three (3) examples. 2+3

2. (a) Write down the major categories and aims of pharmaceutical products.

(b) Briefly state the importance of the regulation of therapeutics. 2+3

3. (a) What is meant by quality control ?

(b) Describe briefly the basic requirements of QC in pharmaceutical industry. 2+3

4. (a) What is the importance of quality assurance ?

(b) Give a brief account of the function of QA in pharmaceutical manufacturing. 3+2

5. (a) State the meaning and importance of GLP.

(b) Summarize the basic requirements of GLP. 2+3

6. With the help of a flow chart illustrate the need to set acceptance criteria for polymorphism in Drug substances and drug product. 5

7. How one will set the acceptance criteria for drug product Dissolution ? 5

8. How will you justify that the drug product contain antimicrobial preservatives or possess inherent antimicrobial activity ? 5
