

[Total No. of Questions - 15] [Total No. of Printed Pages - 2]
(2063)

910

B. Pharmacy 2nd Semester Examination

Chemical and Biological Evaluation

MP-322

Time : 3 Hours

Max. Marks : 60

The candidates shall limit their answers precisely within the answer-book (40 pages) issued to them and no supplementary continuation sheet will be issued.

Note : Attempt any One question from Section A, any three questions from Section B and any Seven questions from Section C.

SECTION - A

1. What do you understand by terms Quality Control and quality assurance? Discuss important precautions and actions required for ideal quality control and quality assurance in pharmaceutical industry. (18)
2. What do you mean to sterility with reference to pharmaceutical production? Discuss the necessary parameters as prerequisite of sterility testing. How sterility testing is performed for large volume parenterals? (18)

SECTION - B

1. Write detailed assay procedure for any one of the following:-
(a) Plague Vaccine (b) Tetanus antitoxin (7)

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2. Discuss theory and procedure employed for microbiological assay of any antibiotic of your choice. (7)
3. Discuss any two official methods employed for pyrogen testing in pharmaceutical industry. (7)
4. What are preservatives? In what formulations the role of preservative is critical to maintain efficacy. Give two methods to test the effectiveness of a preservative. (7)

SECTION - C

1. Comment on personal validation. (3)
2. Discuss briefly Indian pharmacopoeial testing of pyrogen. (3)
3. Give fundamental principle for immunoassay. (3)
4. How quality of purified water is assured? (3)
5. Give principle for biological assay of streptokinase or urokinase. (3)
6. What are essential conditions for expert of pharmaceutical formulations? (3)
7. Give basic principle for bioassay of vitamin B₁₂. (3)
8. Enumerate the sampling techniques used in quality control laboratories. (3)
9. Comment briefly on Drug Information Profile. (3)