[Total No. of Questions - 15] [Total No. of Printed Pages - 2] (2064)

14830

M. Pharmacy 2nd Semester Examination

Chemical and Biological Evaluation

MP-322

Time : 3 Hours **Max. Marks : 90**

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, Three questions from Section B and Seven questions from Section C.

SECTION - A

1. What are different sources of pyrogens? Discuss the chemical nature and impact over the shelf life of a liquid formulation. How they could be destructed? Discuss the detailed procedure of pyrogen testing as per Indian Pharmacopeia.

2. Compare the advantages and disadvantages of chemical assays over the biological assays. Give detailed procedure for the assay of any two of the following—

   (a) Heparin sodium

   (b) Diphtheria antitoxin

   (c) Rabies antiserum (25×1=25)

SECTION - B

3. What is schedule M? Justify the requirements of schedule M for pharmaceutical industry.

4. Discuss theory and procedure employed for microbiological assay of any vitamin of your choice.

5. Discuss the underlying principle for assay of tetanus antitoxin. Enumerate the steps involved in assay procedure.

6. Why validation is an essential parameter for quality control? Enumerate various validation procedures involved in quality control of pharmaceuticals. (10×3=30)

SECTION - C

7. What do you mean by term sterilization with reference to parentral preparations? What type of sterilization are effected to pharmaceutical dosages forms?

8. What do you mean by GLP? Name atleast five essential good laboratory practices to be instituted in quality control laboratory.

9. When a pharmaceutical product is called back from market, how returned product is handled beneficially by the industry.

10. Give a brief account of human immune system. Enumerate the components of immune system exploited by quality control analyse.

11. What are endotoxins? How they could be qualitatively detected?

12. Give brief account of WHO certification for export of pharmaceuticals.

13. How quality of water for injection is estimated?

14. What do you mean by “SOP’s”? Enumerate in product features required for the release of pharmaceutical product from quarentine of the pharmaceutical industry.

15. What do you mean by the following terms?

    (a) Reference standard

    (b) Pharmacopoeia standard.

    (c) API (7×5=35)