M. SC. (Analytical Chemistry) Sem-III (Choice Based Credit & Grade System) : SUMMER - 2019

SUBJECT : ANALYSIS OF PHARMACEUTICALS

Day : Thursday
Date : 02/05/2019

S-2019-1179

Time : 03.00 PM TO 06.00 PM
Max. Marks :60

N. B. :

1) All questions are **COMPULSORY**.
2) Figures to the right indicate **FULL** marks.
3) Answers to both the sections should be written on **SEPARATE** answer book.

SECTION- I

Q.1 Answer **ANY THREE** of the followings: **(15)**

a) Write history of Indian Pharmacopoeia [IP].

b) Discuss the qualification and Duties of Govt. analyst.

c) Write in short requirements for approval of quality control laboratories.

d) Explain the term Drug and Misbranded drug.

e) What does following schedules prescribes:
1) Sch. G 2) Sch. X 3) Sch. P 4) Sch. M 5) Sch. Y

Q.2 Answer **ANY THREE** of the followings: **(15)**

a) Write the objectives of Drug and Cosmetic act 1940.

b) Discuss the principle and apparatus for limit test for Arsenic.

c) What are impurities? Explain the sources of impurities.

d) Explain an Assay of Hydrogen Peroxide (IP).

e) Discuss the Duties of Drug Inspector in relation to manufacturing of drugs.

SECTION-II

Q.3 Answer **ANY THREE** of the followings: **(15)**

a) Define Expiry date. How will you calculate shelf life of drugs.

b) Discuss the standards for tablet.

c) What are emulsion? Discuss the quality control tests for emulsion.

d) Enlist the quality control tests for parentrals. Explain in detail pyrogen test.

e) Define and classify various pharmaceutical additives.

Q.4 Answer **ANY THREE** of the followings: **(15)**

a) Explain teratogenisity and mutagenisity with example.

b) What are suspensions? Write the ideal qualities and quality control test for suspension.

c) Explain the phases of clinical trials with reference to ED^{50} and LD^{50}.

d) What are Capsules? Differentiate between hard gelatin and soft gelatin capsule.

e) Describe ISO guidelines with special emphasis on ISO 9002.

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