Total No. of Questions : 14]

MPA 102 T

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M. PHARMACY DEGREE EXAMINATIONS, JULY - 2022

First Semester

PHARMACEUTICAL ANALYSIS

ADVANCED PHARMACEUTICAL ANALYSIS

Time : **Three Hours** Maximum : **75** Marks

SECTION - A

Answer any FIVE Questions. **5x5 = 25 M**

1. Define Impurities and write the classification of impurities in drug substance (or) Active pharmaceutical ingredients.
2. Write a note on effect of temperature and pH on the stability of drug products.
3. Write a brief note on photostability testing guidelines.
4. Explain the Enzyme Immuno Absorbant Assay.
5. Write the biological tests and assay for Tetanus Antitoxin.
6. Give a brief outline on Accelerated stability testing.
7. Explain the principle and role of PCR studies for gene regulation.

SECTION - B

Answer any FIVE Questions. **5x10 = 50 M**

8. Explain the rationale for the reporting and control of degradation products and listing of degradation products in specifications.
9. Write the Elemental classification and discuss the analytical procedure for C and Nanolysis.
10. Give an account on basics of Impurity Profiling.
11. Explain the protocol and applications of HPTLC fingerprinting in stability testing of phytopharmaceuticals.
12. Discuss the biological tests and assay of
    a) Adsorbed Diphtheria vaccine.
    b) Heparin sodium IP.
13. Explain the separation of bound and unbound drug.
14. Write the applications of Immunoassay and describe Radio Immuno Assay.

Total No. of Questions : 14]

MPA 102 T

[Total No.of Pages : 02

M. PHARMACY (SUPPLE) DEGREE EXAMINATIONS, JANUARY - 2022

First Semester

PHARMACEUTICAL ANALYSIS

ADVANCED PHARMACEUTICAL ANALYSIS

Time : **Three Hours**

Maximum : **75** Marks

SECTION - A

Answer any FIVE Questions. **5x5 = 25 M**

1. Classify residual solvents and write the analytical procedure for any one residual solvent.
2. Briefly explain the analytical procedures for Carbon and Hydrogen elemental impurities.
3. How do you calculate shelf life of drug products ?
4. Outline the regulatory requirements for the stability testing of phytopharmaceuticals.
5. Write the assay and biological tests for Oxytocin.
6. Give an account on Fluoro Immuno Assay.
7. Write a short note on PCR studies for gene regulation.

SECTION - B

Answer any FIVE Questions. **5x10 = 50 M**

8. Define and classify impurities. Describe and draw a flow chart showing schematic representation of qualification techniques for impurity profiling of drugs.
9. Explain the factors affecting stability of drug substance and drug products.
10. What is Impurity Profiling ? Write its importance in testing of pharmaceutical products and add a note an degradent characterisation.
11. Describe the applications of HPTLC and HPLC finger printing in stability testing of phytopharmaceuticals.

[P.T.O.]

12. Explain the different steps involved in production of antibodies.

13. Write the biological tests and assay of

    a) Rabies vaccine.

    b) Heparin Sodium IP.

14. Give a brief account on

    a) Photostability testing guidelines.

    b) Radioimmunoassay.

Total No. of Questions :14] [Total No. of Pages : 02

M.PHARMACY (Regular) DEGREE EXAMINATIONS, FEB/MAR-2020

First Semester

M.PHARMACY

PHARMACEUTICAL ANALYSIS

ADAVANCED PHARMACEUTICAL ANALYSIS

Time: Three Hours **Maximum marks:75**

SECTION-A

Answer any FIVE Questions **5X5=25M**

1. Write the biological assay of Absorbed Tetanus vaccine.
2. Write about Radio Immuno Assay.
3. Explain the sources of Elemental impurities.
4. Describe the ICH guidelines for biological products.
5. What are the different factors effecting on the reaction rates?
6. Write a note on photo stability testing guidelines.
7. Define
   a) Impurity
   b) Stability tests
   c) Biological Assay as per ICH guidelines

SECTION-B

Answer any FIVE Questions **5X10=50M**

8. Write about the sources of impurities and ICH guidelines as on stability studies.
9. Define elemental impurities and write in detail on instrumentation, C,H,N analysis?
10. Write the basics of impurity profiling and different techniques involved for degradant characterisation.

P.T.O

11. How can we perform the stability testing of phyto pharmaceuticals using HPLC?

12. Write about the assay and biological tests for

    a) Human antihaemophilic vaccine

    b) Heparin sodium

    c) Rabies vaccine

13. a) Define Immunoassays and add a note on production of antibodies.

    b) Explain in detail about optical IA and luminiscence IA.

14. Describe briefly about the Impurities in new drug products.

Total No. of Questions :14]

MPA 102 T

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M.PHARMACY (Supply) DEGREE EXAMINATIONS, AUGUST-2019

First Semester

PHARMACEUTICAL ANALYSIS

ADVANCED PHARMACEUTICAL ANALYSIS

Time: Three Hours **Maximum marks:75**

SECTION-A

Answer any FIVE Questions **5X5=25M**

1. Write in brief about regulatory requirements for the stability testing of phytopharmaceuticals.
2. Write a short note on production of antibodies.
3. Write the assay and biological test for diptheria vaccine.
4. What are stability studies? Write its types and importance. Add a note on stability zones.
5. Write classification and sources of elemental impurities. Add a short note on control of them.
6. Write about identification, reporting and qualification of impurities.
7. Explain the principle and applications of RIA and write a short note on immunoassays types.

SECTION-B

Answer any FIVE Questions **5X10=50M**

8. Write the principle, types and steps involved in PCR in detail.
9. Explain about Enzyme immunoassay and Fluoro immunoassay and add applications of immunoassays.
10. Write about the protocol for stability testing of phytopharmaceuticals. Explain HPTLC finger printing of any phytopharmaceutical.
11. Write in detail about ICH stability testing guidelines.

P.T.O

12. Classify impurities and write in brief about ICH guidelines for stability testing of a new drug substance.

13. Write about identification of potential elemental impurities and explain the C and H elemental analysis.

14. Classify and write limits of residual solvents and write about reporting levels of residual solvents.