Total No. of Questions : 14]

MPA 103 T

[Total No.of Pages : 02

M. PHARMACY DEGREE EXAMINATIONS, JULY - 2022

First Semester

PHARMACEUTICAL ANALYSIS

PHARMACEUTICAL VALIDATION

Time : **Three Hours**

Maximum : **75** Marks

SECTION - A

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

1. Write a detailed note on qualification of manufacturing equipments ?
2. Write the qualification of UV-Visible Spectrophotometer ?
3. Explain the procedure involved in validation of pharmaceutical water system and pure system ?
4. Write a note on computer system validation ?
5. What do you mean design qualification and factory acceptance test ?
6. Explain about factors affecting choice of IP protection and penalties for violation ?
7. Define patent and write a note on concepts of intellectual property rights ?

SECTION - B

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

8. a) Define qualification and validation and write the advantages of validation ?

   b) Write a note on performance qualification and re-qualification with examples ?
9. Write the qualification of HPLC and HPTLC analytic instrument with examples ?
10. Write a detailed note on cleaning validation and cleaning method development with examples ?
11. Write in detial about analytical method validationas per USP guidelines ?

P.T.O.

12. Differentiate Indian patent and International patent and write International patent requirements procedures and costs ?

13. a) Write a note on Economic importance and mechanism for protection of intellectual property rights ?

    b) Write the qualification of pippte, volumetric-flask measuring cylinder ?

14. a) Write about validation of compressed air and nitrogen and HVAC system ?

    b) Write a note on installation qualification and operational qualification ?

Total No. of Questions : 14]

MPA 103 T

[Total No.of Pages : 01

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

First Semester

PHARMACEUTICAL ANALYSIS

PHARMACEUTICAL VALIDATION

Time : **Three Hours**

Maximum : **75** Marks

SECTION - A

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

1. Define Validation. Write the advantages of Validation.
2. Explain the qualification of Volumetric Flask and Pipette.
3. Outline the validation of Compressed air.
4. What is GAMPS ? Write its significance.
5. Define Copyright and Trademark and give examples.
6. Give a brief account on Patent infringement.
7. Describe the qualification of Electronic balance.

SECTION - B

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

8. Give an account on Installation qualification and Operational qualification.
9. Discuss the qualification of FTIR and HPTLC.
10. Explain the term cleaning validation. Discuss the steps to be followed in cleaning of equipment.
11. Write the general principles involved in analytical method validation as per ICH guidelines.
12. Describe the validation of pharmaceutical water system and pure steam.
13. Give an account on different types of Patent applications and add a note on Rights of a Patentee.
14. Write a note on
    a) Significance of transfer technology (TOT).
    b) Role of Intellectual property in pharmaceutical industry.

Total No. of Questions :14]

MPA 103 T

[Total No. of Pages : 02

I/II M.PHARMACY (Regular) DEGREE EXAMINATIONS, FEB-2019

First Semester

M.PHARMACY (PHARMACEUTICAL ANALYSIS)

PHARMACEUTICAL VALIDATION

Time: Three Hours

Maximum marks:75

SECTION-A

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

1. Write about the significance of transfer technology.
2. Write a short note on digital significance and GAMP5 & their scope.
3. Write a short note on steps, benefits and applications of cleaning in place.
4. Write in brief about analytical method validation as per USP.
5. Explain preventive maintenance and change management.
6. Explain the parameters that are to be considered for performing operational qualification of UV-Visible spectrophotometer.
7. Write about patent infringement and penalties for violation of IPR.

SECTION-B

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

8. Explain the levels and parameters that are to be considered while performing qualification of GC.
9. Explain in detail about the process of filing and grant of a patent in India.
10. Write a short note on
    a) Electronic records
    b) Cleaning of equipment.
11. Explain the validation of HVAC system and write its need.

P.T.O

12. Give a short note on

a) FAT and SAT

b) Qualification of electronic balance.

13. Explain the following

a) Streamlining of qualification

b) Rights and responsibilities of patentee.

14. Write about cleaning of facilities. What are the different levels of cleaning and how to select them?