Total No. of Questions : 14]

MPA 203 T

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M. PHARMACY (Regular) DEGREE EXAMINATIONS, DECEMBER-2022

Second Semester

PHARMACEUTICAL ANALYSIS

QUALITY CONTROL AND QUALITY ASSURANCE

Time : **Three Hours**

Maximum : 75 Marks

SECTION - A

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

1. Write a brief outline on protocol for conduct of non-clinical testing.
2. Give an account on sanitation in pharma industry.
3. Discuss the quality control tests for secondary packaging materials.
4. Briefly explain the significance and format for writing SOP of analytical instruments.
5. Define IPQC. Outline IPQC tests for capsules.
6. Write a brief note on Aseptic process control.
7. Enumerate on Good warehousing practice in pharmaceutical industries.

SECTION - B

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

8. Discuss in detail the ICH guidelines for QSEM with special emphasis on Q-Series.
9. Give a detailed account on organization and personnel responsibilities, construction and plant layout of pharmaceutical industries.
10. Write a note on CPCSEA guidelines.
11. Write an account on purchase specifications and maintainance of stores for raw materials.

[P.T.O.]

12. Explain

    a) Three tier documentation.

    b) Distribution Records.

13. a) Discuss the types of process deviation and deviation handling.

    b) Write a brief outline on expiry date calculation.

14. Define Quality Audit and discuss the purpose, benefits and implementation of Internal audit system.

Total No. of Questions : 14]

MPA 203 T

[Total No.of Pages : 01

M. PHARMACY DEGREE EXAMINATIONS, JULY - 2022

Second Semester

PHARMACEUTICAL ANALYSIS

QUALITY CONTROL & QUALITY ASSURANCE

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

SECTION - A

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

1. Briefly outline the scope of GLP.
2. Write a short note on hygine and personal records in GMP.
3. Write the quality control tests for closures.
4. Give a brief account on three tier documentation.
5. Write a short note on Mix-ups and cross-contamination in manufacturing operations.
6. Explain Batch Formula Record.
7. Discuss the purchase specifications of stores for raw materials in brief.

SECTION - B

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

8. Discuss in detail the protocol for conduct of non-clinical testing and control on animal house.
9. Give a detailed account on Pharmaceutical inspection convention.
10. Write a note on developing specifications (ICH Q6 & Q3 guidelines).
11. Discuss the objectives and content of SOP. Explain how to write SOP of analytical instrument with an example.
12. Write a note on aseptic process control and packaging in Manufacturing control.
13. Explain Inprocess quality control and finished products quality control for Tablets.
14. Discuss Quality audit plan.

Total No. of Questions : 14] **MPA 203 T**

[Total No.of Pages : 01

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

Second Semester

PHARMACEUTICAL ANALYSIS

QUALITY CONTROL AND QUALITY ASSURANCE

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

SECTION - A

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

1. Explain the terms Quality control and Quality assurance.
2. Give a brief outline on CDER guidelines.
3. Write a brief note on importance of SOP and give an example for SOP of an analytical instrument.
4. Explain Process deviation with an example.
5. Define IPQC and discuss its objectives.
6. What is Quality Audit ? Explain the benefits of Internal audit.
7. Give an account on aseptic process control.

SECTION - B

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

8. Write a note on Report preparation and documentation in Non-clinical testing and outline scope of GLP.
9. Explain Quality control tests for closures and secondary packing materials.
10. Write a note on Master Formula Record and Batch Formula Record.
11. Explain drug product inspection and time limitations on production.
12. Discuss CPCSEA guidelines.
13. Write a note on design, construction and plant layout and sanitation maintainance in pharmaceutical industries.
14. Write a short note on Inprocess quality control and finished products quality control of ophthalmic products.

Total No. of Questions :14]

MPA 203 T

[Total No. of Pages : 02

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

Second Semester

M.PHARMACY

PHARMACEUTICAL ANALYSIS

QUALITY CONTROL & QUALITY ASSURANCE

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

SECTION-A

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

1. Write about Batch Formula Records, its contents & functions.
2. Define and explain the importance of CGMP, GLP, GWP, IPQC and CDER.
3. Write a short note on CPCSEA guidelines and its functions.
4. Explain change control procedures.
5. Write an overview on aseptic processing.
6. Write a short note on electronic data handling in pharma industry.
7. Write about purchase specifications and maintenance of stores for raw materials.

SECTION-B

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

8. What are the types of IPQC tests? Explain the IPQC tests for capsules according to Indian pharmacopoeia.
9. Write the current good manufacturing practices for finished pharmaceuticals as per CFR part 211 of USFDA.
10. What are Q-series ICH guidelines meant for? Explain detail about ICH Q,B guidelines.

P.T.O

11. Explain in detail about quality audit, its types, plans and reports.

12. Write about

    a) Charge in of components

    b) Expiry data calculation

    c) Calculation of yield

    d) Controlling of mixups and contaminations.

13. Write in detail about the specifications and test procedures for raw materials.

14. Define and differentiate quality control and quality assurance & explain the quality control tests for containers and closures.

Total No. of Questions :14]

MPA 203 T

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

Second Semester

PHARMACEUTICAL ANALYSIS

QUALITY CONTROL AND QUALITY ASSURANCE

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

SECTION-A

Answer any FIVE of the following. **5X5=25M**

1. What are the functions of good warehousing practice? How to handle finished goods according to it?
2. Write about CDER, its importance, functions and types of drugs under its regulation.
3. Write a short note on designing, purpose and implementation of internal audit.
4. Discuss in brief about
   a) Processing of intermediates and bulk products
   b) Process deviation with example.
5. Write a short note on animal house management.
6. Write in brief about quality control of glass containers.
7. What is three tier documentation? Explain about Master Formula Record.

SECTION-B

Answer any FIVE of the following. **5X10=50M**

8. Write the objectives, content and format of SOP. Write SOP of any analytical instrument.
9. Write an overview on asceptic process control & its objectives and explain in detail about elements of it.
10. What is the importance and need of IPQC tests? Explain the IPQC tests for tablets according to Indian pharmacopoeia.

P.T.O

11. Explain in detail about pharmaceutical inspection convention, its functions and advantages.

12. Write about ICH Q6 guidelines and explain in detail the general concepts of ICHQ6A guidelines.

13. Explain in detail about the conduct of non-clinical testing, report preparation and documentation of non-clinical data.

14. What is the significance of GMP? Explain the specific requirements for the manufacture of sterile dosage forms according to schedule M.